

RESULTS OF THE EVALUATION OF A SCHOOL-BASED PROGRAM FOR THE PREVENTION OF SUBSTANCE USE AMONG ADOLESCENTS



Eudap Final Technical Report n.2





Author

the EU-Dap Study Group*

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1. Introduction

EU-Dap project has been funded by the European Commission within the Community Public Health Programme in 2002.

The aim of the project was to plan a school-based drug prevention program and to assess its the effectiveness, through a multicentre European randomised trial. Drug prevention has been defined in the project as a complex intervention aimed either at curbing initiation with drugs or at delaying the transition from experimental to addicted behaviour of the following drugs: alcohol, tobacco, cannabis and other drugs. So, effectiveness has been measured as the ability of the program to reduce the prevalence of drug use.

EU-Dap project has been implemented by nine partners (two of them enrolled with own funding) from seven different European countries. All the partners have been actively involved in all project's activities and have been responsible for intervention administration in their country. This collaboration has produced the definition of validated programmes standardised at an European level and, in the same time, adapted to the National context of the partners.

2. Reasons for the project

According to modern models of substance abuse prevention, the use of tobacco, alcohol, and illicit drugs share common determinants, and show a common tendency to develop dependency starting in adolescence (McLellan 2000, Camì 2003). Therefore, preventive interventions should target age groups instead of specific substances (Ashton 2003, Wise 1998, Nestler 1997, Leshner 1997). For this reason, primary prevention in the school setting is believed to be one of the most appropriate strategies to tackle substance use, as well as because schools offer a systematic and efficient way of reaching a large number of young persons (UNICRI 2003).

Existing school-based programmes against substance use have employed different approaches. They can be classified into knowledge-based interventions that aim to build negative attitudes toward drugs; affective interventions based on the assumption that psychological factors place people at risk of use; social skills, including refusal skills and life skills programmes; a variety of combinations of programmes (for example, knowledge plus affective interventions) or alternative approaches, such as interventions encouraging alternative activities to drug use (Tobler 1986).

However, the empirical evidence on effectiveness of such programmes is rather weak. A recent Cochrane Review of school-based interventions to prevent drug use stated that only programmes based on enhancing social skills have some chance of being effective (Faggiano 2005), a conclusion shared by other authors concerning the use of illicit drugs (Tobler 2000)

and, in particular, tobacco smoking (Thomas 2002) and alcohol abuse (Foxcroft 2002). Moreover, most of the studies included in these reviews were conducted in North America: 28 out of 29 RCTs included in the Cochrane Review on drugs were carried out in the U.S. (Faggiano 2005), as well as all 17 studies included in a review of tobacco smoking (Gorman 2005). There may be differences in effectiveness when the same programme is implemented in different cultural contexts. A recent paper from the U.K. (Ashton 2003) underlined both methodological and dissemination problems during the implementation of complex interventions, such as life skills, in an European setting.

3. The EU-Dap intervention: the Unplugged programme

Tobler identified the following components as critical in increasing the effectiveness of school-based interventions (Tobler 2000): (i) interactive curriculum; (ii) information about drugs, including their effects; (iii) focus on personal, social and resistance skills; (iv) emphasis on normative education and reinforcement of awareness that most adolescents do not use substances; (v) structured broad-based skills training such as goal setting, communication skills, and general social skills; (vi) teacher training and support from program developers or prevention experts; (vii) active family and community involvement; (viii) cultural sensitivity for example by including activities tailored to the cultural experience of the classroom (Komro 2002). Starting from these premises, the EU-Dap school programme (called *Unplugged*), based on a comprehensive social influence approach (Komro 2002, Tobler 2000), was especially designed by an expert group including behavioural scientists and public health evaluators.

The *Unplugged* core programme consists of 12 one-hour units delivered weekly by teachers at the participating schools, who attended a 3-day training course. It targets both experimental and regular use of alcohol, tobacco and illicit drugs. The curriculum consists of three parts: the first aims to improve knowledge of risks and protective factors, as well as to build attitudes against substance use; the second focuses on interpersonal skills, beliefs, norms and realistic information about prevalence; the third aims to develop intrapersonal skills, such as coping competences, problem solving/decision making and goal setting. The Intervention Manual is published as Eudap Final Technical Report n.1.

The programme is offered in three formats: class curriculum alone, class curriculum plus side activities involving peers, and class curriculum plus activities involving parents (for details, see www.eudap.net).

4. Study design of the evaluation

The effectiveness of the "Unplugged" programme has been evaluated through a cluster randomized controlled trial utilizing schools as experimental units. In the trial, the intervention was compared with a "usual curriculum" group.

4.1 Source populations and study population

The source population consisted of students attending junior high school classes in the geographical areas corresponding to the centres involved in the study (Table 1).

The choice of the school grade of intervention was based mainly on the feasibility of conducting the follow-up of the students one year or more after the baseline survey, and therefore depended on the age at which students would move to other schools and to what extent they would be split up or remain together.

Schools to be included were required to have at least two classes in the target grade; to be part of mainstream educational system (schools for students with special needs and confessional schools were excluded); to consent to participate in the study; and not to be concurrently conducting other systematic structured interventions against substance use.

4.2 Sample size

Eu-Dap is a *cluster randomized* study – i.e. the entire school is randomly assigned to an intervention arm, although the individual remains the unit of analysis. This procedure reduces the effective sample size, since the outcome correlation within a cluster (class or school) can be expected to be higher than the correlation between clusters. This tendency is measured by the *intraclass correlation coefficient* (ICC) ρ . We estimated the ICC from some recent school surveys of substance use among children of similar age in Sweden and Greece, and found values of up to 0.06 for some items, down to as little as 0.015 for others. The effect on the sample size is that we must increase the required sample size by the inflation factor of

$$1 + (m - 1) \rho$$

over that required under simple random sampling, where m stands for the average size of the cluster (Murray 2004). As the class level is assumed to be the most sensible to identify a cluster we chose the class for estimating the required sample size. Thus, if m=20, it is necessary to almost double the sample size for $\rho=0.05$ (inflation factor 1.95), or to increase it by more than one third if $\rho=0.02$ (inflation factor 1.38).

It was decided to take equal numbers of school in each arm, but to double the number of controls. Thus the number of schools per centre would be a multiple of five; fifteen schools per centre was decided upon. However, two centers, Turin and Stockholm, decided to enroll a

double sample of 30 schools each. Thus, with two classes per school, we expected to recruit $165 \text{ schools } \times 2 \text{ classes } \times 20 \text{ students} = 6,600 \text{ students}.$

With sample sizes in the ratio of 3:2 between intervention and controls, and assuming a relative risk based on the literature of 1.5 between controls and intervention, then in order to carry out a statistical hypothesis test at significance level $\alpha=0.05$ with power 0.80, the total "standard" sample size (that is, ignoring the clustering) needed when the incidence in the control group is 5.0%, 7.5% or 10.0%, is 4,978, 3,250 or 2,387, respectively. Therefore, with 10% incidence in the control groups, we can allow for an inflation factor of 6600 / 2,387 = 2.765, corresponding to an ICC of up to 0.092. For 7.5% and 5.0% incidence, we can allow for ICC'- s up to 0.054 and 0.017, respectively. Therefore, the sample size seems to be more than adequate to allow sensitive comparisons between all interventions and controls. For comparing a single arm against the controls (ratio 1:2), the total sample size required at 10% incidence in the control group is 2,670. This indicates that a maximum ICC of 0.025 permits hypothesis testing at the above significance level (although without adjustment for multiple comparisons) and power. Hence, individual comparisons are also adequately powered, except for rare events.

4.3 Selection and randomisation of schools

In order to achieve a balanced representation of social strata, a stratified sample was drawn from the complete list of schools in each centre's catchment area. The centres' lists of schools were divided into three socio-economic strata using the most reliable data available locally, such as average social status of the catchment area, data from previous surveys or the type of school (for example, vocational or other) if this represented a clear social class indicator. Within each stratum, an equal number of schools was locally selected, until the desired number was reached.

In order to ensure allocation concealment (Hewitt 2005), the assignment of the interventions to the schools was carried out by the coordinating centre of the study (Turin). Computer generated blocks of 4 digits were used to allocate schools within centres: every 5 schools, 2 were assigned to the control group, the remaining three were assigned to one of the intervention arms. In some centres, the number of randomised schools was not a multiple of five, because not enough schools in the area of the study agreed to participate, or because the number of accepting schools was higher than expected (Table 2). No replacement of schools was allowed after randomisation, i.e. after the centres had released to schools the trial arm to which they had been assigned.

All classes belonging to the same school (at least 2 from each school) were included in the same arm. At the individual level, only two exclusion criteria were adopted: incapability of answering the questionnaire or parents' refusal.

4.4 Outcome assessment

To evaluate the effectiveness of EU-Dap interventions compared to usual conditions, theoretically, a before-after comparison is not essential, because homogeneity of baseline conditions between arms would be assured by randomisation. However, because the allocation process is done at the group level, and because selection processes at the cluster level can be expected, imbalance of baseline prevalence cannot be excluded. Thus a baseline survey was conducted to measure the main confounding factors and to verify the success of the randomisation.

A self-completed questionnaire was distributed during the first month of the 2004-2005 school year. The main sections of the questionnaire were: (i) own substance use; (ii) knowledge and opinions about substances; (iii) substance use in the close environment; (iv) family and social environment; (v) school environment and climate; (vi) problems and skills. In order to include already validated questions in the questionnaire, most were derived or adapted from the EDDRA data bank (http://eddra.emcdda.eu.org). In order to test the whole questionnaire, a pilot study was conducted in four centres (Novara, Turin, Stockholm and Portugalete closed to Bilbao) among 263 students.

At least three months after the end of the intervention, a second assessment was carried out using the same questionnaire. Similar evaluations are scheduled to take place after a further one, two and four years.

4.5 Confidentiality

In order to preserve the rigorously anonymous management of the data, yet at the same time enabling a student's reports at follow-up to be linked to his or her first questionnaire, a 9-digit individual code was generated by the student according to instructions printed on the first page of the questionnaire. The code was based on stable personal and parental data to allow the identical code to be generated on subsequent occasions. The reliability of the code was assessed during the pilot study, and a definite code was then built to reduce the risk of errors.

To deal with possible sample attrition at follow-up because of students changing school or class, the names of students participating in the baseline assessment were collected separately by each centre in order to make it possible to trace them subsequently if required.

4.6 Ethical aspects

Given the confidentiality of data collection and processing described above, a general policy on parental informed consent was not adopted. Each centre followed the practice required locally: three centres adopted a passive consent procedure, informing families of the administration of the programme, while others asked for individual active consent. Only one centre needed a local permission from the national educational authority.

4.7 Analysis

The effictiveness of the programme have been evaluated using the following outcomes: **ALO smoking**= at least one cigarette in last 30 days; **Regular Smoking**= at least 6 times in last 30 days; **Daily smoking**= at least 20 times in last 30 days; **ALO drunkenness**= at least once in last 30 days; **Regular drunkenness**= at least 3 times in last 30 days; **ALO cannabis**= at least once in last 30 days; **Regular cannabis**= at least 3 times in last 30 days; **ALO drugs**= at least once of any illicit drug in last 30 days.

The analysis has been fitting a Multilevel regression model (also called Random Effect Model) to adjust for the following factors:

- MODEL 1: cluster effect (to correct the inflated precision due to the lower intraclass variability);
- MODEL 2: cluster effect plus the difference in prevalence among centres;
- MODEL 3: cluster effect plus difference in prevalence plus the *imbalance in the baseline characteristics* (controls have higher prevalences). For this purpose *Daily smoking* (as fixed effect) was included in the model to control for imbalance, because
 it appears to be a more stable variable.

We conducted a descriptive analysis of the baseline prevalences of selected characteristics across study arm and centres. To test for differences in prevalences, Chi-squared tests were performed with Bonferroni adjustments for the multiple comparisons (Westfall 1997).

5. Results

5.1 Enrolment and the baseline survey

A total of 170 schools in nine centres agreed to participate in the study (Table 2) and were then randomised. Twenty-seven schools (15.9%) dropped out following their random allocation to a study arm, but before the baseline survey. The rate of withdrawal from the study varied across study arms, being higher for the intervention arms (23.5% versus 4.4% for controls) (Table 3).

Thus, 143 schools and 345 classes (an average of 2.4 per school) were actually included in the study (Table 2). Of the 7,409 eligible students in these classes (196 students were excluded because of incapability or lack of parental consent), 7,079 (95.7%) participated in the baseline survey in September-October 2004 and were, therefore, included in the study.

Four centres enrolled students in the 7th grade (13 years in Sweden, 12 years elsewhere), two in the 8th grade and three the 9th grade. Apart from age, the only demographic characteristic showing differences between intervention arms and controls at baseline was gender; a smaller proportion of girls was also enrolled in the peer intervention schools compared to controls (Table 4).

5.2 Follow-up survey and study population

6,604 students participated in the follow-up survey (May 2005), at least three months after the completion of the program. 6,370 out of 7,079 (91.5%) baseline questionnaires matched to the corresponding follow-up questionnaire. The matching procedure was based on the anonymous code: it started using all the 9 digits, and followed limiting to 6 codes. A manual linkage was also carried out independently by two researchers, at the level of class (fig 1). The characteristics of the study population are presented in the Table 4.

5.3 Effectiveness of the prevention programme

Table 5 shows the main results of the study. The definite model 3 shows a clear protection for students in the intervention arms compared to controls. Interventions groups smoked 12% less during past 30 days, 14% less in a regular way and 30% less daily, when compared with controls. The frequency of drunkenness in past 30 days was also reduced by 28% and 31% for at least once and regularly respectively, and the consumption of cannabis was reduced by 23 and 24%, ALO and regularly respectively, The use of other drugs, although rare, was reduced by 11%.

Unplugged works, a least in the short-term

- it seems to work better:
 - for alcohol and cannabis than for smoking
 - for higher frequent use than for sporadic users
 - for boys than for girls
- there are big differences in the effectiveness of the program between centers (a north-south gradient, data not shown) that need to be explained.

6. Discussion

This paper presents the study design and the baseline characteristics of the study population of a European multicenter study designed to evaluate the effectiveness of a school-based intervention to prevent the onset of the use of tobacco, alcohol and drugs. This endeavour

mobilized resources from nine regional centres in seven countries, and involved more than 7,000 adolescents in 143 schools.

The evaluation of the effectiveness of primary prevention is becoming a priority for public health as well as for the scientific community. Substance abuse, including tobacco and alcohol use, is actually the predominant health problem in developed countries, accounting for 20% of all deaths and 22% of potential years of life lost (Single 2000). Primary prevention is probably the most efficient way of tackling this problem, but there is still a need for evidence. Public health programmes face different ethical challenges compared to clinical practice. If public health or school authorities carry out an intervention aimed at preventing substance abuse, there should be conclusive evidence that it can alter the natural history of the target condition in a significant proportion of those to whom the intervention is delivered (Cochrane 1989).

Despite the large number of evaluations that have been carried out, evidence on the effectiveness of school-based programmes for the prevention of substance use is still weak and comes mainly from studies in the US (Faggiano 2005, Thomas 2002). Studies from Europe represent a small minority: among those aimed at preventing drug use, only one small study (Hurry 1997) was included in a recent review (Faggiano 2005), whereas among those aimed at preventing tobacco use, some failed to detect any effect (Eveyard 2001) while others show inconsistent results across centres (de Vries 2003).

The EU-Dap study presents some unique features. First, it is an experimental study with a large sample size, providing more power than previous studies for detecting even small effects. Furthermore, the involvement of seven different countries can handle [SM1] the "context shift" from the original US -conceived skills programme. However, multicentre studies often present particular difficulties concerning standardisation of the intervention and the data collection (Lytle 1994). To deal with these issues, a rigorous monitoring procedure was laid down, establishing a continuous flow of standardized information on the process of enrolment of schools, classes and students, as well as on the implementation of the programme activities.

During the recruitment of the study population, an unequal drop-out rate was observed in the intervention arms compared to controls (23.5% among intervention groups versus 4.4% among controls). This was unexpected because previous studies had found the opposite (Schofield 2004, Crone 2003). This fact, however, could easily be explained if a pool of equally motivated schools and class teachers had been initially recruited, but having underestimated the necessary commitment to some degree, a subsequent re-appraisal occurred during the training course.

Whether the imbalance observed across arms in the baseline prevalence is attributable to this process of self-selection is a matter of discussion. 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 cannot be excluded, it seems counter-intuitive and thus unlikely to explain the difference in the drop-out rate. Chance is a more likely explanation, a fact that imposes the need for some caution when inferring balanced individual characteristics after cluster randomisation. Therefore, the importance of collecting baseline data in community experimental studies should be repeatedly emphasized, as this allows baseline characteristics to be taken into account when analysing intervention effects.

Above all, these preliminary data from the EU-Dap trial show that complex multicenter experimental studies can be designed and carried out in Europe, with satisfactory standardization of procedures for the recruitment and allocation of the study populations.

Moreover, the European Commission approved the project Implementation of EU-Dap at a population level (Eudap 2).

The objectives of EU-Dap 2 are the following:

- to conclude the first efficacy phase of EU-Dap1 project with a longer evaluation
- to carry out an effectiveness research by planning and applying at a population level of the prevention program in 8 EU member states for a total of 10 partners (Italy has 3 centres).
- to produce the Intervention Manual new version based on performance analysis and comments of teachers
- to define the procedure for the implementation and dissemination of the Unplugged programme, giving recommendations to policy makers and school authorities on the way to diffuse the programme.

7. References

Ashton B. The American Star comes to England. Drug and Alcohol Findings 2003; 8: 21-26

Camí J, Farré M. Drug Addiction N Engl J Med 2003; 349:975-86.

Cochrane AL. Effectiveness And Efficiency: Random Reflections on Health Services. BMJ Books, 1989.

Crone MR, Reijneveld SA, Willemsen MC, van Leerdam FJ, Spruijt RD, Sing RA.

De Vries H, Mudde A, Kremers S, Wetzels J, Uiters E, Ariza C, VitoÂria PD, Fielder A, Holm K, Janssen K, Lehtovuori R and Candel M. The European Smoking Prevention Framework Approach (ESFA): short-term effects. Health Education Research 2003; 18: 649-663.

Eveyard P, Sherratt E, Almond J et al. The change-in-stage and updated smoking status results from a cluster randomised trial of smoking prevention and cessation using the transtheoretical model among British adolescents. Preventive Medicine 2001; 33: 313-324.

Faggiano F, Vigna-Taglianti FD, Versino E, Zambon A, Borraccino A, Lemma P. School-based prevention for illicit drugs' use.. In: The Cochrane Database of Systematic Reviews 2005, Issue 2. Art. No.: CD003020.pub2. DOI: 10.1002/14651858.CD003020.pub2.

Foxcroft DR, Ireland D, Lowe G, Breen R. Primary prevention for alcohol misuse in young people. The Cochrane Database of Systematic Reviews 2002, Issue 3. Art. No.: CD003024. DOI: 10.1002/14651858.CD003024.

Galanti MR, Siliquini R, Cuomo L, Meleto JC, Perez T, Panella M, Faggiano F and the EU-Dap study group. Yesting anonymous link procedures for follow-up of adolescents in a school-based trial: the eu-dap pilot study. Contemporary publication

Gorman DM. Does measurement dependence explain the effects of Life Skills Training Program on smoking outcomes? Prev Med 2005; 40: 479-487

Hewitt C, Hahn S, Torgerson DJ, Watson J and Bland JM Adequacy and reporting of allocation concealment: review of recent trials published in four general medical journals BMJ 2005; 330: 1057-1058

Hurry J, McGurk H. An evaluation of a primary prevention programme for schools. Addiction Research 1997; 5:23-38

Komro KA, Toomey TL. Strategies to prevent underage drinking. Alcohol Res Health. 2002;26:5-14

Leshner AI. Drug abuse and addiction treatment research: the next generation. Arch Gen Psych 1997;54: 691-694

Lytle LA Davidann BZ, Bachman K, Edmundson EW, Johnson CC, Reeds JN, Wambsgans KC, Budman S.. CATCH: challenges of conducting process evaluation in a Multicentre Trial. Health education Quarterly 1994; Suppl. 2: S129-S141

McLelland T, Lewis DC, O'Brien CP, Kleber HD. Drug dependence, a chronic mecdical disease: Implications for treatment, insurance and outcome evaluation. JAMA 2000; 284: 1689-95

Murray DM, Varnell SP, Blitstein JL. Design and analysis of Group-randomized trials: a review of recent methodological developments. Am J Public Health 2004; 94: 423-32.

Nestler EJ, Aghajanian GK. Molecular and cellular basis of addiction. Science 1997; 278: 58-63

Schofield MJ, Lynagh M, Mishra G. Evaluation of a Health Promoting Schools program to reduce smoking in Australian secondary schools. Health Education Research 2003; 18: 678-692.

Single E, Rehm J, Robson L, Van Truong M. The relative risks and etiologic fractions of different causes of death and disease attributable to alcohol, tobacco and illicit drug use in Canada. CMAJ 2000;162:1669-75

Thomas R. School-based programmes for preventing smoking. *The Cochrane Database of Systematic Reviews* 2002, Issue 2. Art. No.: CD001293. DOI: 10.1002/14651858.CD001293.

Tobler NS, Roona MR, Ochshorn PM, Diana G, Streke AV, Stackpole KM. School-based adolescent drug prevention programmes: 1998 meta-analysis. J Primary Prev 2000;20:275-336.

Tobler NS. Meta-analysis of 143 adolescent drug prevention programmes: quantitative outcome results of a program participants compared to a control or comparison group. J Drug Issues 1986;16:537-67.

UNICRI. School-Based Drug Education: a guide for practioners and the wider community. United Nations Office for Drug Control and Crime Prevention; 2003

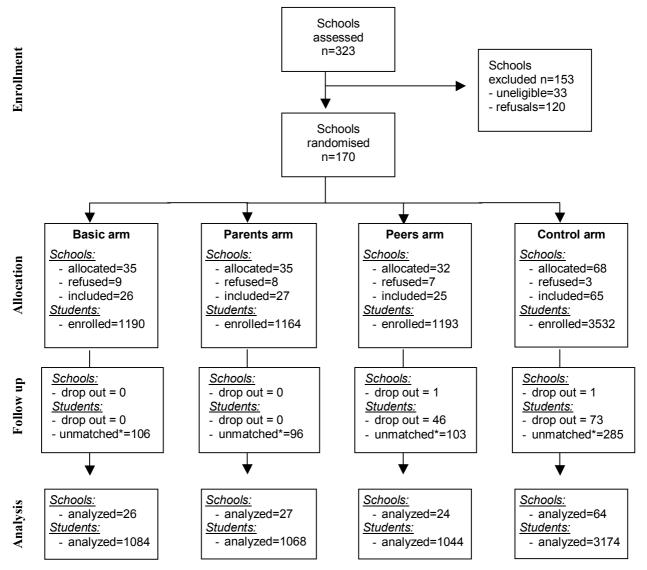
Westfall PH, Wolfinger RD. Multiple Tests with Discrete Distributions. The American Statistician 1997;51: 3 -8.

Wise RA. Drug-activation of brain reward pathways. Drug Alcohol Depend 1998; 51: 13-22



8. Tables and Figures

Figure 1 – Flow-chart of the enrolment of schools and students.



^{*}follow-up questionnaires not matched with baseline questionnaires among students surveyed at baseline and whose class was active in the follow-up survey.

Figure 2. Changes in prevalence of smoking use in the last 30 days between baseline and post-test follow-up

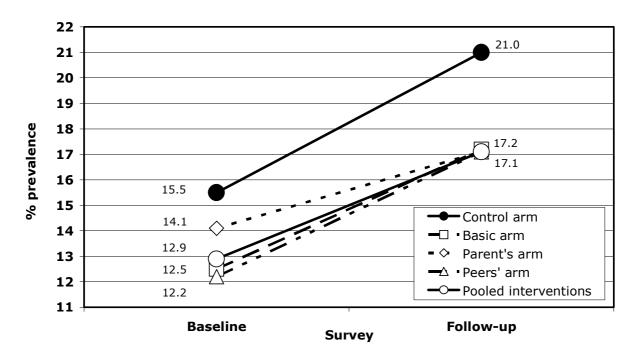
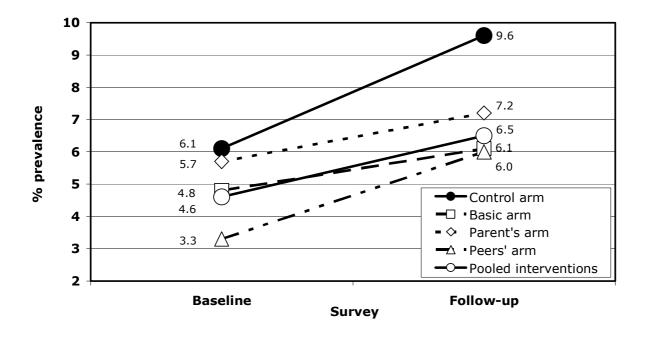


Figure 3. Change in prevalence of daily smoking (>= 20 cigarettes in the last 30 days) between baseline and post-test



 $Table \ 1-Socio\text{-}economic \ characteristics \ of the \ centres \ involved \ in \ the \ Eu-Dap \ study$

Participating Centres	Number of inhabitants	Socioeconomic characteristic
Italy/ Turin	900,000	Industrial city
Spain/ Bilbao	2 million	Mixed tertiary sector, agriculture and industry
Germany/ Kiel	280,000	Mixed tourism, agriculture and industry
Belgium/ Gent	231,000	Mixed tertiary sector, services, education, industry
Sweden/ Stockholm region (excl. Stockholm municipality)	1.1 million	Middle size urban communities
Greece/ Thessaloniki NW region	500,000	Mixed industry and agriculture
Austria/ Wien	1.5 million	Urban technology, tourism, education and administration
Italy/ Novara	100,000	Middle size urban communities
Italy/ L'Aquila	300,000	Mixed tertiary sector, agriculture and industry

Table 2 – Participation (%) in the EU-Dap trial among schools, classes and students (first pre test survey).

	Schools	selected		Enrolled			Students	
Centres	Randomised	Withdrew	Schools	Classes	Students	Eligible*	Participants **	%
Italy/ Turin	30	2	28	78	1750	1727	1660	96.1
Spain/ Bilbao	15	5	10	23	461	456	429	94.1
Germany/ Kiel	15	0	15	29	664	606	592	97.7
Belgium/ Gent	22	9	13	48	753	730	709	97.1
Sweden/ Stockholm	28	5	23	45	1138	1086	1033	95.1
Greece/ Thessaloniki	17	0	17	34	775	775	732	94.5
Austria/ Wien	17	3	14	37	937	927	858	92.6
Italy/ Novara	13	3	10	25	544	537	516	96.1
Italy/ L'Aquila	13	0	13	26	583	565	550	97.3
Total	170	27	143	345	7605	7409	7079	95.5

^{*} *Eligible* differ from *Students* in enrolled *classes* because of incapability of answering the questionnaire or parents' refusal.

^{**} Participants differ from Eligible because of absentees.

 $Table \ 3-Numbers \ of schools \ randomised \ and \ dropping \ out \ after \ randomisation, \ by \ study \ arm \ and \ centre.$

				Total						
	E	Basic	Pa	arent	J	Peer	Co	ntrols		
Centres	Rand.	Drop out	Rand.	Drop out	Rand.	Drop out	Rand.	Drop out	Rand.	Drop out %
Italy/ Turin	6	1	6	0	6	1	12	0	30	6.7
Spain/ Bilbao	3	2	3	2	3	1	6	0	15	33.3
Germany/ Kiel	3	0	3	0	3	0	6	0	15	0.0
Belgium/ Gent	5	3	5	3	4	2	8	1	22	40.9
Sweden/ Stockholm	6	1	6	1	6	2	10	1	28	17.9
Greece/ Thessaloniki	3	0	4	0	3	0	7	0	17	0.0
Austria/ Wien	3	0	3	2	3	1	8	0	17	17.6
Italy/ Novara	3	2	2	0	3	0	5	1	13	23.1
Italy/ L'Aquila	3	0	3	0	1	0	6	0	13	0.0
Total	35	9 (25.7%)	35	8 (22.9%)	32	8 (21.9%)	68	4 (4.4%)	170	27 (15.9%)

Table 4 - Characteristics of the matched population

_				Stud	y arm				A	
<u>-</u>	Ba	sic	Par	ents	Pe		Con	trols	interve	entions
	n	%	n	%	n	%	n	%	n	%
Age										
12 years	376	34.7	243	22.7	379	36.3	1043	32.9	998	31.2
13 years	434	40.0	418	39.1	283	27.1	851	26.8	1135	35.5
14 years	274	25.3	407	38.1	382	36.6	1280	40.3	1063	33.3
School grade										
7th level	582	53.7	422	39.5	495	47.4	1469	46.3	1499	46.9
8th level	228	21.0	239	22.4	167	16.0	425	13.4	634	19.8
9th level	274	25.3	407	38.1	382	36.6	1280	40.3	1063	33.3
Gender										
boys	563	51.9	522	48.9	610	58.4	1629	51.3	1695	53.0
girls	520	48.0	546	51.1	431	41.3	1538	48.5	1497	46.8
missing	1	0.1			3	0.3	7	0.2	4	0.1
Family composition*										
One parent	89	8.2	93	8.7	102	9.8	269	8.5	284	8.9
Both parents	860	79.3	834	78.1	801	76.7	2513	79.2	2495	78.
other	135	12.4	141	13.2	141	13.5	387	12.2	417	13.0
Brothers/sisters*										
yes	898	82.8	868	81.3	877	84.0	2507	79.0	2643	82.7
no	175	16.1	183	17.1	163	15.6	625	19.7	521	16.3
missing	11	1.0	17	1.6	4	0.4	42	1.3	32	1.0
Centres										
Italy/ Turin	203	18.7	225	21.1	206	19.7	859	27.1	634	19.8
Spain/ Bilbao	26	2.4	58	5.4	75	7.2	212	6.7	159	5.0
Germany/ Kiel	111	10.2	122	11.4	125	12.0	203	6.4	358	11.2
Belgium/ Gent	126	11.6	50	4.7	171	16.4	288	9.1	347	10.9
Sweden/ Stockholm	206	19.0	179	16.8	116	11.1	426	13.4	501	15.7
Greece/ Thessaloniki	113	10.4	138	12.9	117	11.2	322	10.1	368	11.5
Austria/ Wien	137	12.6	55	5.1	91	8.7	433	13.6	283	8.8
Italy/ Novara	45	4.1	124	11.6	101	9.7	209	6.6	270	8.4
Italy/ L'Aquila	117	10.8	117	11.0	42	4.0	222	7.0	276	8.6
Socioeconomic status										
High - A	379	35.0	444	41.6	365	35.0	996	31.4	1188	37.2
Medium - B	346	31.9	373	34.9	234	22.4	1124	35.4	953	29.8
Low - C	359	33.1	251	23.5	445	42.6	1054	33.2	1055	33.0

Table 5 - Prevalence Odds Ratios of use in the intervention arms vs control: comparison of results using different models

	Controls	Interventions	Unadjusted	Model 1	Model 2	Model 3
	n/N*	n/N*	PR (95%CI)	POR (95%CI)	POR (95%CI)	POR (95%CI)
ALO smoking	642/3059	531/3098	0.82 (0.74-0.91)	0.87 (0.72-1.04)	0.88 (0.72-1.08)	0.88 (0.71-1.08)
Regular smoking	407/3059	315/3098	0.76 (0.67-0.88)	0.84 (0.66-1.06)	0.85 (0.65-1.10)	0.86 (0.67-1.10)
Daily smoking	294/3059	200/3098	0.67 (0.57-0.80)	0.73 (0.56-0.95)	0.74 (0.55-0.99)	0.70 (0.52-0.94)
ALO drunkenness	363/3112	265/3145	0.72 (0.62-0.84)	0.72 (0.58-0.89)	0.74 (0.60-0.92)	0.72 (0.58-0.90)
Regular drunkenness	123/3112	77/3145	0.62 (0.47-0.82)	0.63 (0.44-0.89)	0.65 (0.46-0.92)	0.69 (0.48-0.99)
ALO cannabis	230/3157	157/3179	0.68 (0.56-0.83)	0.77 (0.60-0.99)	0.77 (0.61-0.98)	0.77 (0.60-1.00)
Regular cannabis	141/3157	92/3179	0.65 (0.50-0.84)	0.75 (0.55-1.03)	0.77 (0.57-1.03)	0.76 (0.53-1.09)
ALO drugs	294/3171	224/3191	0.76 (0.64-0.89)	0.84 (0.66-1.07)	0.85 (0.67-1.09)	0.89 (0.69-1.15)

^{*.} Number of users out of the total number of students answering the question at follow-up (unadjusted model). PR. Prevalence Ratios (all interventions vs control).

Model 1. Multilevel model (RIGLS bin 1st order MQL) with 3 levels (level 1: centre; level 2: class; level 3: student)

Model 2. Multilevel model (RIGLS bin 1st order MQL) with 3 levels adjusting for centre prevalence of daily smoking
Model 3. Multilevel model (RIGLS bin 1st order MQL) with 3 levels adjusting for centre prevalence of daily smoking and baseline status of the outcome

Table 6 - Prevalence Odds Ratios of effectiveness interventions, compared to controls, by intervention arm

	Study arm									
	Contro	ol		Basic		Parents		Peers		
	n/N*	PR	n/N*	POR (95%CI)	n/N*	POR (95%CI)	n/N*	POR (95%CI)		
ALO smoking	605/2968	1	165/996	0.97 (0.71-1.33)	171/1001	0.80 (0.59-1.09)	160/982	0.89 (0.65-1.21)		
Regular smoking	387/2968	1	93/996	0.81 (0.56-1.19)	110/1001	0.85 (0.59-1.24)	94/982	0.90 (0.64-1.27)		
Daily smoking	277/2968	1	61/996	0.64 (0.41-1.01)	75/1001	0.72 (0.47-1.12)	57/982	0.75 (0.49-1.16)		
ALO drunkenness	353/3054	1	87/1044	0.79 (0.57-1.09)	72/1029	0.61 (0.44-0.85)	94/1010	0.82 (0.60-1.12)		
Regular drunkenness	120/3054	1	22/1044	0.66 (0.37-1.19)	26/1029	0.67 (0.40-1.13)	28/1010	0.76 (0.47-1.24)		
ALO cannabis	225/3130	1	43/1066	0.79 (0.54-1.16)	56/1058	0.76 (0.53-1.09)	53/1026	0.79 (0.54-1.16)		
Regular cannabis	137/3130	1	26/1066	0.83 (0.47-1.45)	34/1058	0.75 (0.45-1.25)	28/1026	0.75 (0.44-1.28)		
ALO drugs	293/3156	1	61/1082	0.80 (0.56-1.15)	85/1066	0.98 (0.69-1.38)	76/1037	0.89 (0.64-1.25)		

^{*.} Number of users out of the total number of students answering the question at follow-up (multilevel adjusted model).

PR. Prevalence Ratios (all interventions vs control) estimated using multilevel model 3 (RIGLS bin 1st order MQL with 3 levels adjusting for centre prevalence of daily smoking and baseline status of the outcome)

Table 7 - Prevalence Odds Ratios of effectiveness of interventions, compared to controls (POR=1), stratified by gender

		All			Boys			Girls	
	Control	Intervention		Control	Intervention		Control	Intervention	
	n/N*	n/N*	POR (95%CI)	n/N*	n/N*	POR (95%CI)	n/N*	n/N*	POR (95%CI)
ALO smoking	605/2968	496/2979	0.88 (0.71-1.08)	304/1509	220/1563	0.88 (0.66-1.18)	300/1453	276/1412	0.86 (0.65-1.15)
Regular smoking	387/2968	297/2979	0.86 (0.67-1.10)	211/1509	126/1563	0.68 (0.50-0.93)	175/1453	171/1412	1.07 (0.74-1.55)
Daily smoking	277/2968	193/2979	0.70 (0.52-0.94)	159/1509	80/1563	0.49 (0.34-0.71)	117/1453	113/1412	0.99 (0.64-1.52)
ALO drunkenness	353/3054	253/3083	0.72 (0.58-0.90)	209/1548	136/1623	0.64 (0.49-0.85)	143/1501	117/1456	0.86 (0.63-1.18)
Regular drunkenness	120/3054	76/3083	0.69 (0.48-0.99)	80/1548	51/1623	0.68 (0.45-1.04)	39/1501	25/1456	0.66 (0.37-1.18)
ALO cannabis	225/3130	152/3150	0.77 (0.60-1.00)	161/1596	88/1668	0.62 (0.45-0.85)	63/1528	64/1478	1.05 (0.70-1.58)
Regular cannabis	137/3130	88/3150	0.76 (0.53-1.09)	106/1596	54/1668	0.60 (0.40-0.91)	30/1528	34/1478	1.17 (0.59-2.33)
ALO drugs	293/3156	222/3185	0.89 (0.69-1.15)	194/1615	115/1686	0.64 (0.48-0.86)	97/1534	107/1495	1.40 (0.95-2.04)

^{*.} Number of users out of the total number of students answering the question at follow-up (multilevel adjusted model).

PR. Prevalence Ratios (all interventions vs control) estimated using multilevel model 3 (RIGLS bin 1st order MQL with 3 levels adjusting for centre prevalence of daily smoking and baseline status of the outcome)

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