# STUDY PROTOCOL

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## 1. Background

Drug addiction is commonly described from both the medical and the social point of view as a chronic, relapsing disease, characterised by the effects of the prolonged use of the drug itself and by the behavioural disorder due to its compulsive seeking (Leshner 1997).

There is no doubt that, once it is established, addiction "is often an uncontrollable compulsion to seek and use drugs" (Leshner 1999). However, at least two groups of drug users have been identified, the "sensation seekers" and people using drug "as a way to deal with life's problems or with dysphoric mood". Moreover, not all of the initial users progress from experimental use to drug addiction. In fact, it is widely accepted that *experimental use* is typical of adolescents, who "use drugs simply for the pleasant feelings or the euphoria that drugs can produce, or to feel accepted by their peers" (Leshner 1999). Even if individual vulnerability, due to neurological or psychological susceptibility, has to be taken into account, "even occasional drug use can inadvertently lead to *addiction*" (Leshner 1997; Leshner 1999). To explain the origins of addiction, other authors suggest the "stepping-stone hypothesis". According to this, drug use follows culturally determined steps, for example hard liquors and tobacco are defined to be an intermediate step between beer/wine and marihuana, while marihuana represents a further step to other illicit drugs (Kandel 1975). Considering that these are not alternative explanatory models, whichever model of explanation is chosen, primary interventions should aim both to prevent initiation (from a population point of view, to reduce incidence of the first use), and to block the progression, i.e. the transition from *experimental use* to *addiction*. Specific intervention models could choose to aim to a unique approach; cigarette smoking, for instance, is a prototype of the latter approach, in so far initiation is nearly universal, while progression concerns 30-50% of the triers; the progression from marihuana (prevalence of lifetime use >30%) to hard drugs (prevalence <5%) could be a target both of a intervention aimed to reduce initiation or to reduce progression (Siliquini, 2001).

Taking into account these models and the modern theories (Wise 1998; Nestler 1997), the addiction can be considered as unique problem, whatever the object may be, and the preventive interventions must target age categories instead of specific problems. This approach takes into account that our understanding of the dynamics and determinants of drug abuse is far from satisfactory (Green 1991).

### 1.1 The role of the school in prevention of use of drugs

So, schools are appropriate for alcohol, illicit drugs and tobacco use prevention programming; four out of every five persons who use tobacco begin before they reach adulthood. Prevention of substance use should therefore focus on school-age children and adolescents. Schools offer the most systematic and efficient way to reach a significant number of students each year. School staff can target youths at a young age before their beliefs about smoking and other substance use have been established.

The specific interventions for the prevention of substance initiation must be aside and not instead to the development and enforcement of reasonable school policies. Clearly articulated school policies, applied fairly and consistently, can help students decide not to use tobacco, alcohol and illicit drug use (CDC 94). The school policy should cover:

- An explanation of the rationale for preventing drug use (e.g. tobacco is the leading cause of death, disease and disability)
- Prohibitions against use of smoking, alcohol and other drug use by students, all school staff and visitors on school property, in school vehicles and at school-sponsored functions away from school property.
- Prohibitions against alcohol and tobacco advertising in school buildings, at school functions and in school publications.
- Provisions for students and all school staff to have access to programs to help them quit using drugs.
- Procedures for communicating the policy to students, all school staff, parents or families, visitors and the community.

As outlined before, school-based interventions to do not need to be substance specific, inasmuch preventing tobacco use can also contribute to prevent the use of illicit drugs, but it is an advantage if such programs are also designed to prevent the use of all substances.

## 1.2 School-based interventions against substance use

Most prevention of substance use in the school environment is based on behavioural theory (Kelli 2002, Tobler 2000), and aims at reducing the onset of adolescents' alcohol, tobacco and drug use by decreasing personal and social risk factors and by strengthening personal and social protective factors (Ennet, 2003).

Several studies have compared the effectiveness of different school-based interventions. Life Skills (Botvin et al. 1995), Project Northland (Perry, 1996), The Midwestern Prevention Project (Pentz, 1989), Project SMART (Hansen, 1991) and Project ALERT (Ellickson, 1993) are examples of school-based prevention programs teaching adolescents resistance-, general- social. and personal skills. Although the prevention program with a higher impact in the reduction of drug initiation appears to be the Life Skills model (Faggiano, 1994), results from most projects generally show a small effect on tobacco use, and inconsistent effects on alcohol and drug use (Ashton, 2000, Tobler, 2000).

These programs have been mostly developed in North America, a fact which may imply differences in effectiveness, when implemented in other cultural contexts. A recent paper from U.K. (Ashton, 2003) underlines both methodological and dissemination problems in the implementation of complex interventions such as Life Skills in a European setting.

In an extensive meta-analysis Tobler shows that an interactive curriculum is more effective than a noninteractive one in preventing illicit and legal drug use among adolescents (Tobler, 2000). Tobler further identifies several components that are critical in increase in effectiveness of school-based intervention (Tobler, 2000). These components are: i. appropriate information about drugs, including information on short-term effects and long-term consequences; ii. focus on personal, social and resistance skills, helping to identify internal (e.g. anxiety and stress), as well as external (e.g. peer and advertising) pressures; iii. emphasis on normative education and reinforcement of awareness that most adolescents do not use alcohol, tobacco or other drugs; iv. structured broad-based skills training such as goal setting, stress management, communication skills, general social skills and assertiveness skills; v; teacher training and support from program

developers or prevention experts; vi. active family and community involvement; vii. cultural sensitivity- for example by including activities that require teacher and student input and which can be tailored to the cultural experience of the classroom (Kelli, 2002).

### 1.3 The EU-Dap project

It is possible to estimate that in almost all the junior-high and high schools in Europe an intervention against the use of smoking, alcohol and drugs is carried out every year. Most of these are programs that has never been evaluated with scientific methodology, for which no information exists on the true impact on substance use behaviour of youth. This is a particularly serious problem for some reasons: on one hand, as already mentioned, the theory about the origin of drug use is still weak, so that non solid interventions can be based on it; on the other hand the evaluations of the efficacy carried out by now present many limitations: in some cases evidence is acquired on the impact of the intervention on intermediate outcomes, like knowledge or modification of some skills, instead on the ability to modify the frequency drug use initiation or of prevalence of that risk factor (e.g. the effectiveness of the preventive program in reducing regular smoking in youth). Of the interventions assessed with appropriate design, some indicated a reduction of drug use in the target populations (Pentz 1989), whereas the majority revealed no differences between study group and controls (Botvin 1995; Dejong 1987), and a few reported even an increase in the use of drugs following the intervention (Dukes 1997; Hawthorne 1996). It is useful to remind the outcome of a widespread prevention program, Life Education, the authors of which stated: "When the data are extrapolated to the state-wide smoking and drinking estimates, these showed that of all smoking among year 6 schoolchildren, 25% of girls' and 19% of boys' smoking could be attributed to participation in Life Education, as could 22% of all boys' recent drinking". The authors conclude that "The findings suggest that intervention programmes should be thoroughly evaluated prior to widespread implementation…" (Hawthorne 1996). From the ethical point of view, it is absolutely not acceptable that an intervention, carried out without an expressed need, could cause harm (Gillon, 1994)

In the absence of substance use prevention programs with solid evidence of effectiveness, there is a need for a sound evaluation of programs carried out especially in the European countries. The EU-Dap project aspires to fill this gap of knowledge coring out an evaluation of an intervention program especially conceived starting from the components and characteristics of interventions that scientific literature have indicated by now as the most useful in reducing substance use prevalence (Tobler 2000, Faggiano, 2004).

The ambition of EU-Dap researchers is to give to European school and health authorities some information useful to implement effective interventions to prevent the drug abuse and to implement methods for the evaluation of the effectiveness of interventions in schools.

EU-Dap is a project funded by the European Commission (European Public Health programme 2002 grant # SPC 2002376).

## 2. Objectives of the study

The aim of this project is to contribute to the production of evidence concerning the effectiveness of drug prevention programs. Drug prevention is defined here as:

- a complex intervention

- aimed either to curb initiation with drugs
- or to delay the transition from experimental to addicted behaviour
- of the following drugs: tobacco, alcohol, cannabis and other drugs.

The project aims to assess the effectiveness of a school-based drug prevention program in Europe by a multicentric evaluation. The program, based on behavioural theory (Kelli 2002, Tobler 2000), has been especially made by the EU-Dap IPG group, and are presented in a separate document (EU-Dap IPG group, 2004). Together with the basic intervention, EU-Dap includes the independent evaluation of the impact of two other components: the involvement of parents and the involvement of peers. So, altogether, the study will evaluate three different interventions, by means of three different intervention groups:

- behavioural intervention alone;
- behavioural intervention plus the involvement of parents;
- behavioural intervention plus the involvement of peers.

## 3. Study design

The evaluation will be carried out by a randomised controlled cluster design (RCCT). The three school-based interventions will be compared with a non-intervention group. The assignment of the intervention to the classes will be done randomly by the coordinating centre of the study. The design of the randomisation will be done by means of a stratified design to take into account specific socio-demographic characteristics of the included centres. The baseline characteristics on the drug consumption (alcohol, tobacco, marijuana and other drugs) will be compared with the prevalence of consumption after one year. Longer follow-ups, 2, 3 and 5 years, are foreseen and will be subject for an extension of the project.

## 4. Study base and study population

The base of the study is the scholar population of the Centres involved in the study (see table).

| Participating Centre | # of inhabitants | SE characteristic | Coordinator | # of schools / # of students to involve |
|---|---|---|---|---|
| GREECE **North-west region of Thessaloniki** | 500.000 | Mixed industry and agriculture | Greece REITOX Focal Point | 15/600 |
| SPAIN **Comunidad Autonoma del Pais Basco** | 2 million | Mixed terciary sector, agricolture and industry | EDEX | 15/600 |
| GERMANY **Kiel** | 280.000 | Mixed tourism, agriculture and industry | IFT – Nord Institute for Theraphy and Health Research | 15/600 |
| BELGIUM | | | De Sleutel | 15/600 |

| | | | | |
|---|---|---|---|---|
| **Merelbeke** | | | | |
| ITALY **Novara** | 100 000 | middle urban communities | University of Eastern Piedmont | 15/600 |
| SWEDEN **Stockholm region (excluded Stockholm municipality)** | 1.1 million | Large and middle urban communities | Centre for Tobacco Prevention - Stockholm centre of Public Health | 30/1200 |
| ITALY **Torino** | 900 000 | Industrial town | OED –University of Torino | 30/1200 |
| AUSTRIA **Wien** | 1.562.482 million | Urban technology, tourism, education + administration | Institut fur social-und Gesundeits Psycologie | 15/600 |
| Total | | | | 150/6000 |

4.1 Target population:

The criteria for the choice of the scholar grade to be submitted to intervention are the following:

4.1.1 the natural history of smoking and other drugs behaviour: the age of students must be under the modal age of prevalence;

4.1.2 the prevalence at the 1 year follow-up: it needs to be higher enough to allow detection of differences;

4.1.3 the probability to stay 2 year or more within the same "scholar building" for follow-up purposes;

Taking into account these criteria the age strata involved in the study is:

- 13 years for Germany, Greece, Austria, Sweden
- 14 years for Italy (and perhaps for Spain and Belgium)

4.2 The criteria for inclusion of schools are the following:

- to have at least 2 classes in the grade under study (to be reviewed in the next week);
- to be a "normal" school: special profiles, such as institutes for mentally retarded people, confessional or foreign languages schools are excluded;
- willingness to be included in the study with at least 2 classes of the grade of interest;
- not involvement in other specific interventions with strong packages targeted to the grade of interest.

The process for the assignment of schools to a study arm is made up by 4 steps, whose results have to be registered in the flow-diagram annexed:

First step: definition of the area of the study and list of the schools of the base-population under study. All schools having the scholar grade under study take part to the study base. A data-base of that schools as to be built by each centre.

Second step: the schools not meeting the structural inclusion criteria (e.g. less than 3 classes, special profiles, etc.) are excluded and the reasons for exclusion registered in the *school data-base*. If the characteristics for exclusion are not already known by the centres, the schools can be included in the list of the eligible schools and will be excluded after the first contact.

Third step: The eligible schools have to be classified in 3 groups of approximately equal size according to the **stratification variable** (social class). The social classification have to be done by centres using the more specific available way (e.g. social conditions of the area of the basin of the school, type of school etc) and, if it is not attainable using current data, it have to be asked directly to schools. The criterion of social classification has to be described and attached to the school data-base. T

Fourth step: To random stratified sample of the eligible schools have to be done to select the schools to be enroled. Using Excel, a table has to be filled in as follows:

| **STRATUM 2** | | **STRATUM 2** | | **STRATUM 3** | |
|---|---|---|---|---|---|
| **SCHOOL** | | **SCHOOL** | | **SCHOOL** | |
| School a | | School a | | School a | |
| School b | | School b | | School b | |
| School c | | School c | | School c | |
| .... | | .... | | .... | |

The strata should be approximately the same number of schools.

Within each stratum a random number have to be assigned to each school in the sample using a the random function of Excel (=*random()*), and the list has to be ordered consequently. Be careful because the random digit change any time you ask for ordering! After the first ordering, do not perform other ordering (I will check with Luca if there is a method to avoid this problem). After this operation the table will appear as follows:

| **STRATUM 2** | | **STRATUM 2** | | **STRATUM 3** | |
|---|---|---|---|---|---|
| **SCHOOL** | **Random digit** | **SCHOOL** | **Random digit** | **SCHOOL** | **Random digit** |
| .... | 0,308057 | .... | 0,403366 | School b | 0,453731 |
| School b | 0,410060 | School c | 0,66681 | School a | 0,308057 |
| School a | 0,415495 | School a | 0,872282 | .... | 0,890821 |
| School c | 0,634273 | School b | 0,952007 | School c | 0,964998 |

Starting from the top of the list of schools in each strata, ordered by the random digit, the needed number (5 in the first extraction) of schools is extracted from each strata. The head-masters is then contacted in order to obtain the agreement for participation in the study, and/or to obtain information on the exclusion criteria. If a school denies the participation or

turns out ineligible, it is replaced at once with the following school in the same stratum. This process will be continued until the needed number of schools is reached.

The replacement of dropped out schools can be done with the same procedure until the definite allocation to the intervention harm is done. All information on this process is registered in the school data-base, which is then sent to the Torino centre for the randomisation.

For this process the following tools will be prepared:

- the data-base for the follow-up of the process
- the letter for the involvement request
- the general project description to be annexed to the request

## 5. Sample size

Eu-Dap is a *cluster randomized* study – although the child is the unit of analysis, the children are grouped into classes and schools, and the entire school is randomized to an intervention arm. This procedure reduces the effective sample size, since there is a tendency for there to be greater similarity between the results for two children from the same cluster, compared to two children from different clusters. This tendency is measured by the *intraclass correlation* coefficient $\rho$. Our estimates from some school surveys in Sweden and Greece show that it would be wise to allow for a value of $\rho = 0.05$, although it could be as low as 0.02 for some items. The effect on the sample size is that we must increase the required sample size by the inflation factor of

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

where m stands for the average size of the cluster. 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).

There now follow some "standard" calculations of the necessary sample size (that is, ignoring the clustering), after which we will see what size of intraclass correlation can be allowed for.

Table 1 (below) shows sample size calculations for the comparison of *one* intervention arm to the control, with equal numbers in each group, assuming that, we will carry out a test of statistical significance at the conventional levels of $\alpha = 0.05$ and power 0.80, and assuming a relative risk based on the literature of 1.5 (control:intervention, i.e. 0.67 for intervention:control). These figures will remain the same in subsequent tables.

Table 1. Sample sizes for comparing two percentages (e.g prevalence of smoking), between one intervention group and a control group. Note: no allowance for intraclass correlation.

| % in controls | % in intervention group* | Sample size | |
|---|---|---|---|
| | | Per group | Total |

| | | | |
|---|---|---|---|
| 2.5 | 1.7 | 4,952 | 9,904 |
| 5.0 | 3.4 | 2,425 | 4,850 |
| 7.5 | 5.0 | 1,583 | 3,166 |
| 10.0 | 6.7 | 1,162 | 2,324 |
| 12.5 | 8.4 | 909 | 1,818 |
| 15.0 | 10.1 | 741 | 1,482 |

*approximate

It is clear from this that the one-to-one comparison is not at all powerful for the currently proposed sample size. However, we will consider comparing the data from all three intervention arms together against the controls. The necessary sample sizes are as follows in Table 2

Table 2. Sample sizes for comparison of pooled data from 3 interventions against the control group. Note: no allowance for intraclass correlation.

| % in control group | Sample size in | | |
|---|---|---|---|
| | Control | Intervention* | Total |
| 5 | 1,555 | 4,666 | 6,221 |
| 7.5 | 1,016 | 3,048 | 4,064 |
| 10 | 746 | 2,239 | 2,985 |
| 12.5 | 585 | 1,754 | 2,339 |
| 15 | 477 | 1,430 | 1,907 |

*Total for the 3 interventions

Thus, if we look at an outcome with 10% incidence in the control group, the proposed sample size of 960 per arm will allow for an inflation factor of 960 / 746 = 1.287, which corresponds to $\rho = 0.015$ for $m = 20$.

To increase the power of the study will enrol 15 schools with a the ratio of intervention:controls = 3:2. We get the following:

Table 3. Sample sizes for comparison of pooled data from 3 interventions against 2 control groups. Note: no allowance for intraclass correlation.

| % in control group | Sample size in | | |
|---|---|---|---|
| | Controls | Interventions | Total |
| 5 | 1,991 | 2,987 | 4,978 |
| 7.5 | 1,300 | 1,950 | 3,250 |
| 10 | 955 | 1,432 | 2,387 |

| | | | |
|---|---|---|---|
| 12.5 | 747 | 1,121 | 1,868 |
| 15 | 609 | 914 | 1,523 |

In this scenario, we have 30 classes per centre = 600 children per centre = 4,800 children in the study, assuming 20 per class. Therefore, with 10% incidence in the control groups, we can allow for an inflation factor of 4,800 / 2,387 = 2.011, corresponding to an intraclass correlation of 0.053 – the figure it seems to be necessary to aim for. For 7.5% incidence, we can allow for $\rho$ = 0.025, which is also acceptable for some comparisons.

Assuming

- commonly employed values for statistical tests ($\alpha$ = 0.05, power = 0.80)
- intervention effect corresponding to RR = 1.5 (control: intervention)
- class size of 20

Each centre recruits 15 schools, with two classes per school. These are divided between three strata representing the socioeconomic divisions of the area, 5 per stratum. Within each stratum, one school is assigned at random to each of the 3 intervention arms and the remaining 2 schools are controls.

Two centers, Torino and Stockholm, will try to enroll a two-fold sample of 30 schools. With this supplement of schools the total sample of students should reach 6000 students and 150 schools.

## 6. Random allocation of intervention

The randomisation will identify (see box 1):

- The schools to be involved in each intervention arm;
- The schools to be act as control. For these schools, any intervention can't be proposed for the year of the study. The possibility to propose the intervention to the classes of the grade under study, but 1 year after the start of the study, is under discussion.

For centres having more schools available for randomisation than needed, the residuals schools will not participate to the study. These schools can be involved in the intervention, if desired.
The randomisation procedure consists, within each centre

- To make out a list of the schools included in the sample (15 for each centre and 30 for Turin and Stockholm);
- To assign a random digit to each;
- To order schools for the random digit;
- To assign the intervention on the basis of the order in the list: first 3 school intervention 1, second 3 school intervention 2 and so on;

The intervention assignment will be then communicate to the centres.

## 7. Number of classes to enrol in each school

The schools included must have, for the inclusion criteria discussed before, at least 3 classes for the grade of interest, but at least 2 classes need to be included. Considering the opportunity to include more classes for power reasons, each centre can decide to ask for inclusion from 2 to the total number of classes available in each school. To avoid selection bias, the choice of the number of classes to include for each school must be communicated to all schools before the random allocation to the intervention. In the case of a centre choosing to enrol more than 2

classes, the possible negotiation with the Head master of the school to reduce, for school's reasons, the number of classes to be involved, must also be done before the random allocation and this rule must be respected until the end of the study.

## 8. Ethical aspects

The main ethical problem raised by the study is the right for protection of student data. For this purpose all the procedures of the data gathering, analysis and publication are protected by a rigorous anonymousness. To deal with this constraint, the data from the different questionnaires used in the study will be anonymous-linked as follows:

- all the questionnaires are anonymous: they are identified by a self-generated code based on personal and parental data, not available to EU-DAP researcher and usually not available to the schools, and on an algorithm unknown to the school;
- the self-generated code is used to link data from baseline and follow-up questionnaires;
- the names and addresses of participating students are collected because they are essential for the follow-up purposes. They are accurately kept by centres with due confidentiality;
- all procedures of the study will be driven by the self-generated code. The linkage between the names of the list of participants and the codes of the questionnaires will never be performed.

The code is based on stable personal and parental data (see annex 2) to allow identical code generation for any questionnaire filled in at any time. The code will be generated by participant at any questionnaire completion and for this reason the first sheet of all questionnaire contains instructions to generate it. The common procedures for the completion of codes are the following:

- the inquirer explain the principles of the self code generation;
- the questionnaires are distributed to participants;
- the participants fill in the personal code under the surveillance of the inquirer;
- the enquirer invite the participants to tear off the frontal sheet of the questionnaire and to deliver it to enquirer;
- the enquirer ensure that al the frontal sheet has been collected and then can destroy them.

To verify the reliability of the self-generation of individual codes, a pilot study will be carried out in October 2003 (see attached protocol).

## 9. Baseline questionnaire

The aim of the program is to reduce the age-specific prevalence of use of the following drugs: tobacco, alcohol, marihuana and other drugs.

The prevalence of initial and regular use before and after the interventions represents the study outcome. Theoretically, the comparison before-after is not essential because of the homogeneity of the randomised populations, but, because of the allocation process is done at a group level, it could be useful to estimate the size of the changes within groups.

For this reason a pre-test evaluation will be done to measure the main confounding factors and to testify the success of the randomisation. A self-completed questionnaire will be distributed

during the first month of the scholar year 2003-2004 to evaluate the use of the substances under study and to collect socio-demographic and other data.

The main sections of the questionnaire are:

- social environment;
- own substance use;
- knowledge & opinions about substances
- substance use in the nearest environment;
- family and social environment;
- school environment and school climate
- problems and skills

One year after the intervention start a second assessment will be done. In order to evaluate the long-term effectiveness of the program a similar evaluation is scheduled after 2, 3 and 5 years.

the self-generated anonymous code will be used to link pre-test questionnaire with post-test evaluations while protecting the personal identification. This system has the purpose to prevent the linkage between personal identifiers allowing at the same time the linkage between the different questionnaires filled in by the same subject.

With the aim to include already validated questions in the questionnaire, most of the questions have been catched from the EDDRA data bank (). The complete list of the sources of the questionnaire is shown in following table.

| **Question #** | **Sources** |
|---|---|
| (1) | EMCDDA (1) |
| (2) | EMCDDA (1) |
| (3) | HBSC 1986, 1990,1994, 1998 REVISED *(modified)* |
| (4) | EMCDDA (1) *(modified)* |
| (5) | ESPAD03 *(modified)* |
| (6) | HBSC 1986, 1990, 1994,1998 (C15) *(modified)* |
| (7) | EMCDDA(11) *(modified)* |
| (8) | HBSC 1986, 1990,1994,1998 (C17-C19) *(modified)* |
| (9) | Espad 1995 *(modified)* |
| (10) | EMCDDA(11) *(modified)* |
| (11) | ESPAD03 *(modified)* |
| (12) | ESPAD03 *(modified)* |
| (13) | ESPAD03 *(modified)* |
| (14) | ESPAD 2003 *(modified)* |
| (15) | EMCDDA(11) *(modified)* |

| Question # | Sources |
|---|---|
| (16) | EMCDDA (10) *(modified)* |
| (17) | EMCDDA(8) *(modified)* |
| (18) | rating (swedish cohort) |
| (19) | rating (swedish cohort) |
| (20) | ESPAD03 qu34 |
| (21) | HBSC/Control of Adolescent Smoking (EC Biomed Programme project) 1998 |
| (22) | HBSC 1998 Canadian national questionnaire *(modified)* |
| (23) | ESPAD 03 qu39 |
| (24) | EMCDDA(6) |
| (25) | BRIEF FAMILY LIFE QUESTIONNAIRE |
| (26) | Espad03 (A1) *(modified)* |
| (27) | Espad03 (A1) d |
| (28) | HBSC 1986, 1990, 1994,1998(C10), rating (swedish cohort) |
| (29) | Rating (swedish cohort) |
| (30) | HBSC 1986,1990,1994,1998(C11) |
| (31) | HBSC 1994, 1998 (F10-F12) REVISED |
| (32) | ESPAD 03 qu37 *(modified)* |
| (33) | EMCDDA(4) |
| (34) | rating (Swedish cohort): *(modified)* |
| (35) | EMCDDA (12) |
| (36) | EMCDDA (3) |
| (37) | Fit 5-6 Stell dir vor. (Germany) |

## 10. Pilot study

The aims of the Pilot Study are the following:

1. Test of the application of the link algorithm
2. Test-retest reliability of the algorithm
3. Test of anonymous link procedures (e.g. class list identification)
4. Test retest reliability of a preliminary questionnaire form
5. General acceptance of the assessment questions
6. Test of cost/efficiency of input options (i.e. optical scanning, manual inputting)

The participants will be the following centres: Greece, Italy-Turin, Italy-Novara, Spain, Sweden

The study, scheduled for September-November 2003, will be coordinated by the Stockholm center. See the attached protocol fro details.

## 11. Intervention and training of participants

Intervention implementation

Control of the process

## 12. Outcomes questionnaire

The primary outcome of the study was defined through behavioural endpoints regarding the use of tobacco and drugs, and alcohol drinking. Changes in knowledge, skills, attitudes and intention to use substances in the future were regarded as secondary outcomes. Information on behavioural and psychometric outcomes was collected using a self-completed anonymous questionnaire encompassing 37 items. Behavioural questions on tobacco and alcohol investigated the prevalence of lifetime use, use in the past year and past month as well as current use. Questions on drug use and episodes of drunkenness were limited to lifetime use, past year and past month. Although most items were retrieved from instruments provided in the Evaluation Instruments Bank of the EMCDDA (see http://eib.emcdda.europa.eu/), a test-retest evaluation of repeatability was conducted before using them in the main study (data not shown).

Apart from language adaptation, the questionnaire was identical in all countries. The surveys were conducted in the classroom without teachers' participation. No biochemical validation of self-reported behaviour was planned, since adolescents' self reports in anonymous surveys show high reliability.

## 13. Follow-up procedures

These procedures are designed to reach students that drop out from the school during the follow-up period.

## 14. Time schedule of the study

| | | |
|---|---|---|
| October 2003 | Pilot study: first distribution of the pilot questionnaire | |
| November 2003 | Pilot study: second distribution of the pilot questionnaire | |
| December 2003 | Transmission of data base of pilot study | |
| January 2004 | Transmission of the Participation Questionnaire to schools | |
| May 2004 | Transmission of the list of schools to be randomised to the Turin Centre | |
| August-September 2004 | Training of teachers | |
| October 2004 | Submission of the pre test questionnaire | |
| October 2004-January 2005 | Intervention (limited to the Intervention arms) | |

| | | |
|---|---|---|
| May 2005 | Submission of the first post test questionnaire | |

## 15. Data analysis

From the information on substance use, the following eight outcome variables will be made, all of them with reference to the 30 days preceding the survey: i. any cigarette smoking; ii. Frequent cigarette smoking, defined as smoking six or more cigarettes; iii. daily cigarette smoking, defined as smoking 20 or more cigarettes; iv. any episode of drunkenness; v. frequent drunkenness, defined as three or more episodes; vi. any cannabis use; vii. frequent cannabis use, defined as use on three occasions or more and; viii. any use of illicit drugs, including the following: cannabis, cocaine, heroin, amphetamine, crack, ecstasy, LSD or hallucinogens, GHB, tranquillizers without medical prescription. All outcome variables were analyzed as dichotomous (yes/no).

The adoption of the past 30 days' frequency of use is based on the observation that lifetime use of alcohol or other drugs is a poor predictor of adolescents' future likelihood of using hard drugs, whereas frequency in the past few weeks is a more accurate predictor. Further observations stated that drunkenness is a stronger predictor of subsequent increase in alcohol consumption than average current use.

Prevalence Odds Ratios (POR) and their corresponding Confidence Intervals (95% CI) will be calculated as the measure of association between experimental conditions (all intervention arms pooled together) and behavioural outcome.

In order to take into account the hierarchical structure of the data and the cluster effect, a multilevel modelling approach will be followed in the analysis of the data. Data will be analyzed with MLwiN 2.02 software. Since it is considered to lead to unbiased estimates, Restricted Iterative Generalized Least Square (RIGLS) estimation procedure will be used to estimate the random parameters. Marginal Quasi Likelihood (MQL) and 'first order' will be then selected to include estimated residuals in the RIGLS procedure, and to control the degree of approximation.

## 16. Publication rules

This rules apply to original publications, either national or international, in paper or in congresses, and either to multicentric and local results. They do not apply to reports of the process data useful for internal reasons (state of the art presentation, fund rising etc).

They are based on the statement that the results of the multicentric study are propriety of the SCG, whereas the local results are propriety of centres, even if submitted to the rules presented here.

All papers (or abstracts for the oral presentations) need to be approved by the SCG or by SCG's delegates before publication.

All publications, either original or secondary (e.g translations of already published papers) have to be sent to the coordinating centre, who is the responsible for the collection and dissemination of all materials published by EU-Dap;

The dissemination will occur mainly by the Web Site, but other means can be foreseen;

The publication of the multicentric results must come first than those the local results.

The authorship rules:

- the authorship of each paper will contain the persons who actually worked in the paper, *and the EU-Dap group*. The components of this group, provided as a note to the text, are the components of the SCG *(the addition of some names will be decided at each time)*
- the authorship will be based on the specific contribution in drafting and revising the paper
- the first author is the responsible for the drafting and the revision of the paper;
- a detailed contributorship (i.e. the esplicit definition of actions done by each author) will be prepared for each paper

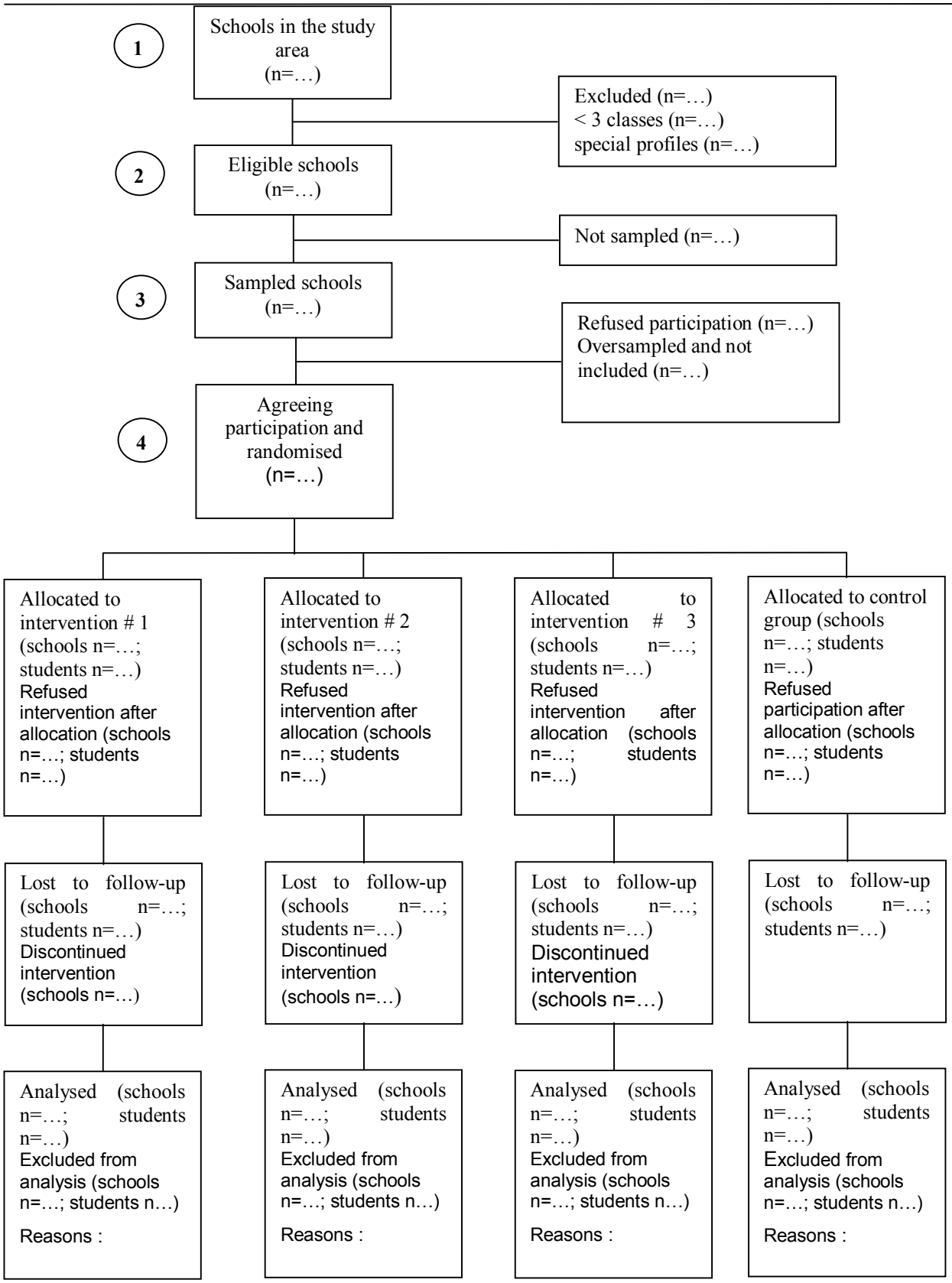
The responsibility for the drawing up of a paper can be either assigned by the SCG or requested to.

In all the publications a statement have to be add on the source of funds of the study, as follows:

*EU-Dap is a project funded by the European Commission (European Public Health programme 2002 grant # SPC 2002376). (add all the relevant national grants).*

## 17. References

1. EU-DAP Intervention Planning Group. Intervention Manual (attached)
2. Botvin reference




Box 1 – School selection procedure