

# European drug addiction prevention trial

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<b>Registration date</b> 30/03/2007	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 15/08/2014	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

Not provided at time of registration

## Study website

<http://www.eudap.net>

## Contact information

### Type(s)

Scientific

### Contact name

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

# Study information

## Scientific Title

## Acronym

EU-Dap

## Study objectives

In most European junior and senior high schools, some kind of intervention to protect against the use of alcohol, tobacco and drugs takes place. Most of these programs, however, have never been evaluated through a rigorous scientific methodology, which is a particularly serious problem. First of all, the theory about the nature of drug use is still weak, causing many interventions to be based on invalid principles. Next, efficacious evaluations completed so far have not drawn firm conclusions to base decisions. In some cases, merely the ability of the intervention to modify knowledge or a few skills was studied. In other cases, the methodology was unsound, for example there was no control group to make a comparison.

In the absence of substance use prevention programs with solid evidence of effectiveness, there is a need for sound evaluation of programs, especially in European countries. The EU-Dap project was created to fill this gap in knowledge.

The intervention program "Unplugged" was specifically designed for European schools, using principles and methods indicated in the scientific literature as being the most useful in reducing the prevalence of substance use.

The EU-Dap trial was designed in order to assess the effectiveness of the "Unplugged" program in preventing the use of tobacco, alcohol and drugs in European junior high schools.

The behaviors of the students regarding lifetime and past 30 days use of cigarettes, cannabis and other drugs; frequency of alcohol drinking and episodes of drunkenness were of interest of the study, as well as knowledge and opinions about substances, and social and personal skills.

Protocol can be found at <http://www.eudap.net/PDF/EU-DAP%20Study%20Protocol%2020-6-04.pdf>

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

A general policy on informed consent was not adopted. Each center followed the practice required locally in order to obtain permission from the corresponding Ethical Boards.

## Study design

Multi-centre cluster randomised controlled trial

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

**Study setting(s)**

Other

**Study type(s)**

Prevention

**Participant information sheet****Health condition(s) or problem(s) studied**

Drug addiction

**Interventions**

The EU-Dap school prevention programme "Unplugged", targeted to 12-14 years old students, was designed to tackle both experimental and regular use of alcohol, tobacco and illicit drugs (for details, see [www.eudap.net](http://www.eudap.net)). It is based on a comprehensive social influence approach, incorporating aspects of normative education, general self-management, personal and social competence skills and knowledge enhancing classes. It was designed by an expert group including behavioural scientists and public health evaluators. The basic curriculum consists of 12 one-hour units to be delivered weekly by class teachers who previously attended a 2.5 days training course. In order to assess the role of parents and of age-peers in enhancing the effectiveness of the basic curriculum, this was delivered in three formats: basic curriculum alone (basic arm), or with the addition of side activities involving either peers (peers arm) or parents (parents arm). The curriculum and the additional components were delivered in the different countries in a very standardized way, concerning both content and the implementation procedures. For instance, the training course for the teachers participating in the programme was led by pedagogists who had received training on the programme during an international course held at the central level.

**Intervention Type**

Other

**Phase**

Not Specified

**Primary outcome measure**

The primary outcome of the study was defined through behavioural endpoints regarding the use of tobacco and drugs, and alcohol drinking.

**Secondary outcome measures**

Changes in knowledge, skills, attitudes and intention to use substances in the future were regarded as secondary outcomes.

**Overall study start date**

15/09/2004

**Completion date**

15/06/2008

**Eligibility**

**Key inclusion criteria**

The study population consists of students 12 to 14 years of age, attending junior high grades in the administrative areas of the participating centers. Criteria for the selection of the age group were the usually low prevalence of substance use and the feasibility of two-years follow-up during compulsory school attendance. Inclusion criteria for the schools were:

1. Presence of at least two classes in the target grade
2. To be part of the mainstream national educational system (schools for students with special pedagogic needs and confessional schools were excluded)
3. Consent to participate
4. Not currently conducting structured interventions against substance use

**Participant type(s)**

Patient

**Age group**

Child

**Lower age limit**

12 Years

**Upper age limit**

14 Years

**Sex**

Both

**Target number of participants**

165 schools, 330 classes, 6600 students

**Key exclusion criteria**

Schools for students with special pedagogic needs and confessional schools, and schools currently conducting structured interventions against substance use were excluded.

Exclusion criteria at the students level were: own incapability to participate in the survey or parents refusal to allow participation.

**Date of first enrolment**

15/09/2004

**Date of final enrolment**

15/06/2008

**Locations****Countries of recruitment**

Austria

Belgium

Germany

Greece

Italy

Spain

Sweden

**Study participating centre**

**via Solaroli 17**

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## **Sponsor information**

**Organisation**

Piedmont Centre for Drug Addiction Epidemiology (OED) (Italy)

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**Sponsor type**

Government

**Website**

<http://www.oed.piemonte.it>

## **Funder(s)**

**Funder type**

Government

**Funder Name**

European Commission. European Public Health Programme 2002 (grant ref: SPC 2002376)

# Results and Publications

## Publication and dissemination plan

Not provided at time of registration

## Intention to publish date

## Individual participant data (IPD) sharing plan

## IPD sharing plan summary

Not provided at time of registration

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Other publications</a>	publication on study design and baseline characteristics of the study population	01/02/2007		Yes	No
<a href="#">Results article</a>	results on anonymous link procedures	01/02/2007		Yes	No
<a href="#">Results article</a>	main results	01/11/2008		Yes	No
<a href="#">Results article</a>	results on gender-specific effects	01/09/2009		Yes	No
<a href="#">Results article</a>	results	01/12/2013		Yes	No