

***An effective school-based prevention
program for tobacco, alcohol and
drugs:
the EU-Dap cluster randomised trial***

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Background

- in developed countries, substance abuse (incl, tobacco and alcohol), accounts for:
 - 20% of all deaths and
 - 22% of YPLL (Single 2000)
- tobacco, alcohol, and illicit drugs share common determinants, natural history, and neurological pathways of abuse liability (McLellan 2000, Di Chiara 2000);
- the incidence of first use increases rapidly from early adolescence (Kandel 1993).
- School is an appropriate setting for drugs use prevention programs

Background

- Cochrane reviews established that programs based on **Social influence approach** have some efficacy in
 - reducing drug use (Faggiano 2005),
 - results for tobacco and alcohol were less convincing (Thomas 2002; Foxcroft 2002):
- more recent studies show effects in delaying smoking onset (Griffin 2002, Crone 2003).
- On the other hand:
 - **some programmes can make harm** (Dukes 1997; Hawthorne 1996)
 - most evaluation studies were carried out in North America or in Australia (**concern for generalisation**)

Methods

- **EU-Dap** is an experimental study
 - involving 9 centers in 7 European Countries
 - funded by European Commission (*Public Health Program*)
 - supported by EMCDDA
- for the evaluation of a school program (called “**Unplugged**”)
 - to prevent tobacco, alcohol and drugs onset
 - especially conceived by an internal expert group



 **GERMANY / Kiel**
IFT-Nord

 **BELGIUM / Gent**
De Sleutel

 **SWEDEN / Stockholm**
Centre for Tobacco
Prevention

 **AUSTRIA / Wien**
ISG

 **SPAIN / Bilbao**
EDEX

 **ITALY / L'Aquila**
University of L'Aquila



 **GREECE / Thessaloniki**
REI TOX/PYXI DA

 **ITALY / Turin**
Piemonte
Monitoring Centre
for Drug Abuse

ITALY / Novara
Medical Sciences Dept
/ Avogadro University

The program “Unplugged”

- is based on a ***comprehensive social influence approach***
 - including the following components:
 - social skills
 - personal skills
 - knowledge
 - normative education
- delivered by the class teachers, trained with a 3-days training course
- composed by 12 one-hour units delivered weekly from October 2004 to January 2005

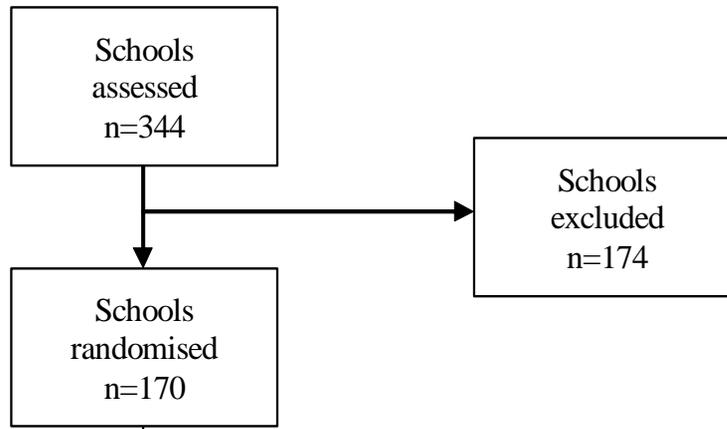
Design of the evaluation

- EU-Dap is a ***Cluster randomised controlled trial***
 - schools were randomised
 - students were the unit of analysis
- The schools to be included were selected by chance among all schools of the centre area
- A stratified randomisation was carried out to ensure a balanced sample according to ***social status***

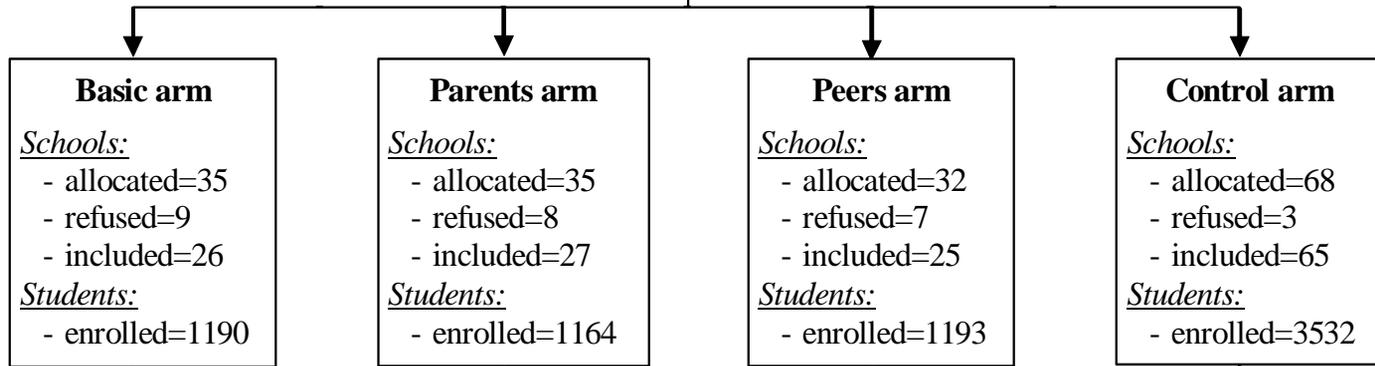
Enrollment

- 7079 students were enrolled at the **baseline survey** (November 2004)
- 6604 participated to the **follow-up survey** (May 2005), at least 3 months after the completion of the program

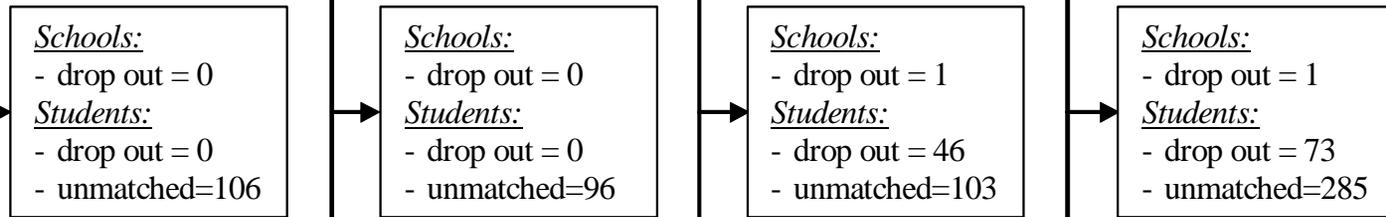
Enrollment



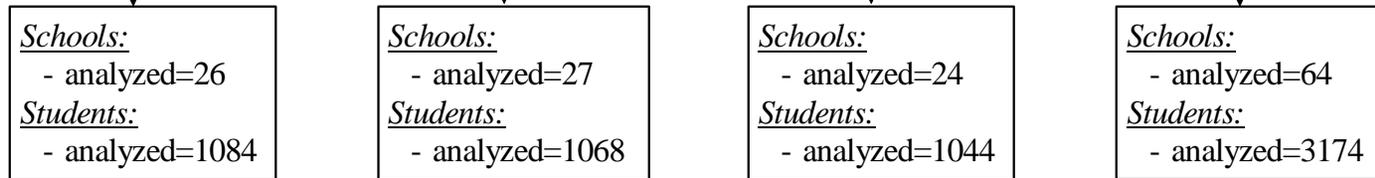
Allocation



Follow up



Analysis



Questionnaire

- Self completed **anonymous** questionnaire on use of substances, attitudes, knowledge...
 - most items retrieved from **EDDRA data bank**
 - identical for all countries
- Linkage between pre- and post-test by a **self generated code** based on fixed data (some letters from name of parents, date of birth..)
- the **reliability** was tested in a pilot study (Galanti 2006)

Baseline-followup matching

- 6370 out of 7079 (91.5%) baseline questionnaires matched to the corresponding follow-up questionnaire
 - the matching procedure started using all the 9 digits of the anonymous code, and followed limiting it to 6 digits
 - the last step was a manual linkage, carried independently by 2 researchers, at the level of class

Characteristics of the analysis sample

	Study Arm					
	Controls		Pooled interventions		Total population	
	(N=3297)		(N=3307)		(N=6604)	
	n	%	n	%	n	%
Gender						
boys	1629	51.3	1695	53.0	3324	52.2
girls	1538	48.5	1497	46.8	3035	47.6
missing	7	0.2	4	0.1	11	0.2
Age						
12 years	1043	32.9	998	31.2	2041	32.0
13 years	851	26.8	1135	35.5	1986	31.2
14 years	1280	40.3	1063	33.3	2343	36.8

Characteristics of the analysis sample

	Study Arm					
	Controls		Pooled interventions		Total population	
	(N=3297)		(N=3307)		(N=6604)	
	n	%	n	%	n	%
Centres						
Italy - Turin	859	27.1	634	19.8	1493	23.4
Spain - Bilbao	212	6.7	159	5.0	371	5.8
Germany - Kiel	203	6.4	358	11.2	561	8.8
Belgium - Gent	288	9.1	347	10.9	635	10.0
Sweden - Stockholm	426	13.4	501	15.7	927	14.5
Greece - Thessaloniki	322	10.1	368	11.5	690	10.8
Austria - Wien	433	13.6	283	8.8	716	11.2
Italy - Novara	209	6.6	270	8.4	479	7.5
Italy - Aquila	222	7.0	276	8.6	498	7.8

Outcomes measures

1. **Any smoking**= at least one sigarette in last 30 days
2. **Frequent Smoking**= at least 6 times in last 30d
3. **Daily smoking**= at least 20 times in last 30d
4. **Any drunkenness**= at least once in last 30d
5. **Frequent drunkenness**= at least 3 times in last 30d
6. **Any cannabis**= at least once in last 30d
7. **Frequent cannabis**= at least 3 times in last 30d
8. **Any drugs**= at least once of any illicit drug in last 30d

Some preliminary considerations

- There is a clear **imbalance** (statistically significant for some outcomes) between controls and intervention arms
 - it is limited to 2 centres and the only explanation is chance
- There are very small (and statistically non significant) differences among the **study arms**
 - for power considerations, the following analysis will be done pooling together intervention arms

Adjusted analysis

- Following adjustments are needed:
 1. to control for the **cluster effect** (i.e. to correct the **inflated precision** due to the lower **intraclass variability**)
 2. to correct for the **imbalance in the baseline characteristics**
 3. to control for the **differences in prevalence** among centres

Adjusted analysis

- a **Multilevel regression model** (*Random Effect Model*) was fitted
 - with 3 levels - center, class, student
 - **baseline variables** to control for imbalance
 - **daily smoking** (as fixed effect) to control for differences in prevalence

Crude effects

	CTRLs	INTs	Crude
	n/N*	n/N*	PR (95%CI)
Any smoking	642/3059	531/3098	0.82 (0.74-0.91)
Frequent smoking	407/3059	315/3098	0.76 (0.67-0.88)
Daily smoking	294/3059	200/3098	0.67 (0.57-0.80)
Any drunkenness	363/3112	265/3145	0.72 (0.62-0.84)
Frequent drunkenness	123/3112	77/3145	0.62 (0.47-0.82)
Any cannabis	230/3157	157/3179	0.68 (0.56-0.83)
Frequent cannabis	141/3157	92/3179	0.65 (0.50-0.84)
Any drug	294/3171	224/3191	0.76 (0.64-0.89)

Adjusted effects

	Multilevel		
	POR (95%CI)	ARR	NNT
Any smoking	0.88 (0.71-1.08)	2,5%	40 (188-22)
Frequent smoking	0.86 (0.67-1.10)	1,9%	54 (459-29)
Daily smoking	0.70 (0.52-0.94)	2,9%	35 (66-24)
Any drunkenness	0.72 (0.58-0.90)	3,3%	31 (57-21)
Frequent drunkenness	0.69 (0.48-0.99)	1,2%	82 (305-47)
Any cannabis	0.77 (0.60-1.00)	1,7%	60 (223-34)
Frequent cannabis	0.76 (0.53-1.09)	1,1%	93 (989-49)
Any drug	0.89 (0.69-1.15)	1,0%	98 (-255-41)

Gender differences

	Boys	Girl
	POR (95%CI)	POR (95%CI)
Any smoking	0.88 (0.66-1.18)	0.86 (0.65-1.15)
Frequent smoking	0.68 (0.50-0.93)	1.07 (0.74-1.55)
Daily smoking	0.49 (0.34-0.71)	0.99 (0.64-1.52)
Any drunkenness	0.64 (0.49-0.85)	0.86 (0.63-1.18)
Frequent drunkenness	0.68 (0.45-1.04)	0.66 (0.37-1.18)
Any cannabis	0.62 (0.45-0.85)	1.05 (0.70-1.58)
Frequent cannabis	0.60 (0.40-0.91)	1.17 (0.59-2.33)
Any drug	0.64 (0.48-0.86)	1.40 (0.95-2.04)

Discussion (i)

- **Unplugged** appears to work, with PORs from 0.80 to 0.70, across all conditions under study
- Weaknesses:
 - short term effects
 - in any case a delay
 - the large majority of studies showing initial positive effects tended to maintain long-term reductions (Skara 2000)
 - imbalance among controls and intervention
 - a presumable effect of chance
 - controlled by inclusion of baseline level of the variable
- strengths
 - large sample size
 - context heterogeneity

Discussion (ii)

- Major issues to discuss
 - lack of effect of the added components (parents and peers involvement)
 - lack of effect for girls
 - Specific effect of **Unplugged** or general effect of **Comprehensive social influence approaches**?

Conclusions

- Unplugged is the first program with evidence of effectiveness in European context for multiple substances of abuse
- **Eu-Dap 2** is recently started:
 - to continue the follow-up
 - to review the Intervention Manual according to performance analysis
 - to prepare a **Dissemination Guidance**, for policy makers and school authorities on the way to diffuse the programme
 - to test in the field the effectiveness of **Guidance**

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Thank you

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