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**Closing Conference of  
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for Parents and  
Professionals**

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**Short-term effectiveness  
of the EU-Dap program**





# Background: (I)

## School is an appropriate setting for illicit drugs use prevention programs

- **4 out of 5** drug users begin before adulthood
- a large number of **adolescents** can be reached
- schools can adopt and enforce a broad spectrum of **educational policies**



# Background: (II)

**In European countries virtually all schools carry out interventions to prevent the onset of substance use**

- most are theory-based
- some have been evaluated as regards intermediate variables (knowledge, intentions...)
- the evaluation of effectiveness in reducing use of drugs is very rare

**There is a solid suspicion that some programmes**

**can make harm**

(Dukes 1997; Hawthorne 1996)



# Background: (III)

## Why is that important to apply effective programs

- **Primary prevention intervention:**
  - the target population is **healthy**, our aim is to prevent a risk behaviour (use of drugs) in a population where most people are **non-users**
- **We are responsible for adolescents who start using drugs because of the intervention**
- **Adolescents are involved**
- The target population **did not ask for an intervention**



# Background: (IV)

- Considering the risk of harm, on the ethical point of view the ***evaluation of effectiveness*** of prevention programs is essential

## Focuses of this presentation

- Cochrane Review on ***School-based prevention for illicit drugs' use*** (Faggiano, 2005)
- short-term results of the **EU-Dap trial**



# Systematic reviews



- ❖ **Systematic reviews** are a tool developed to summarize the results of scientific literature
- ❖ They are the base of the **Evidence Based Medicine**
- ❖ The **Cochrane Collaboration** is an international no-profit network aimed at developing systematic reviews on the effectiveness of health technologies (medicines, interventions) using standardized methods
- ❖ Cochrane Library ([www.cochrane.org](http://www.cochrane.org))



# Rationale for the review



Because of the **huge variability** in the effectiveness of school-based programs for the prevention of **drugs use**

A systematic review has been considered a priority by the **Cochrane Drug and Alcohol Review Group** (CDAG)





# Reference



**This review was published in the Cochrane Library  
(Issue 2 – 2005):**

**"School-based prevention for illicit drugs' use"**

**Authors:**

**Faggiano F, Vigna-Taglianti FD, Versino E,  
Zambon A, Borraccino A, Lemma P**





# Methods



All **RCTs** and **CPS** (Controlled Prospective Studies) evaluating **any intervention program versus a control condition** were considered

The following databases were searched (from beginning to feb 2004)

- Medline & Embase
- ERIC, Sociological Abstracts, Psycinfo
- Cochrane databases

To discover unpublished researches/results, **research teams, and 18 authors of included and excluded studies** were contacted

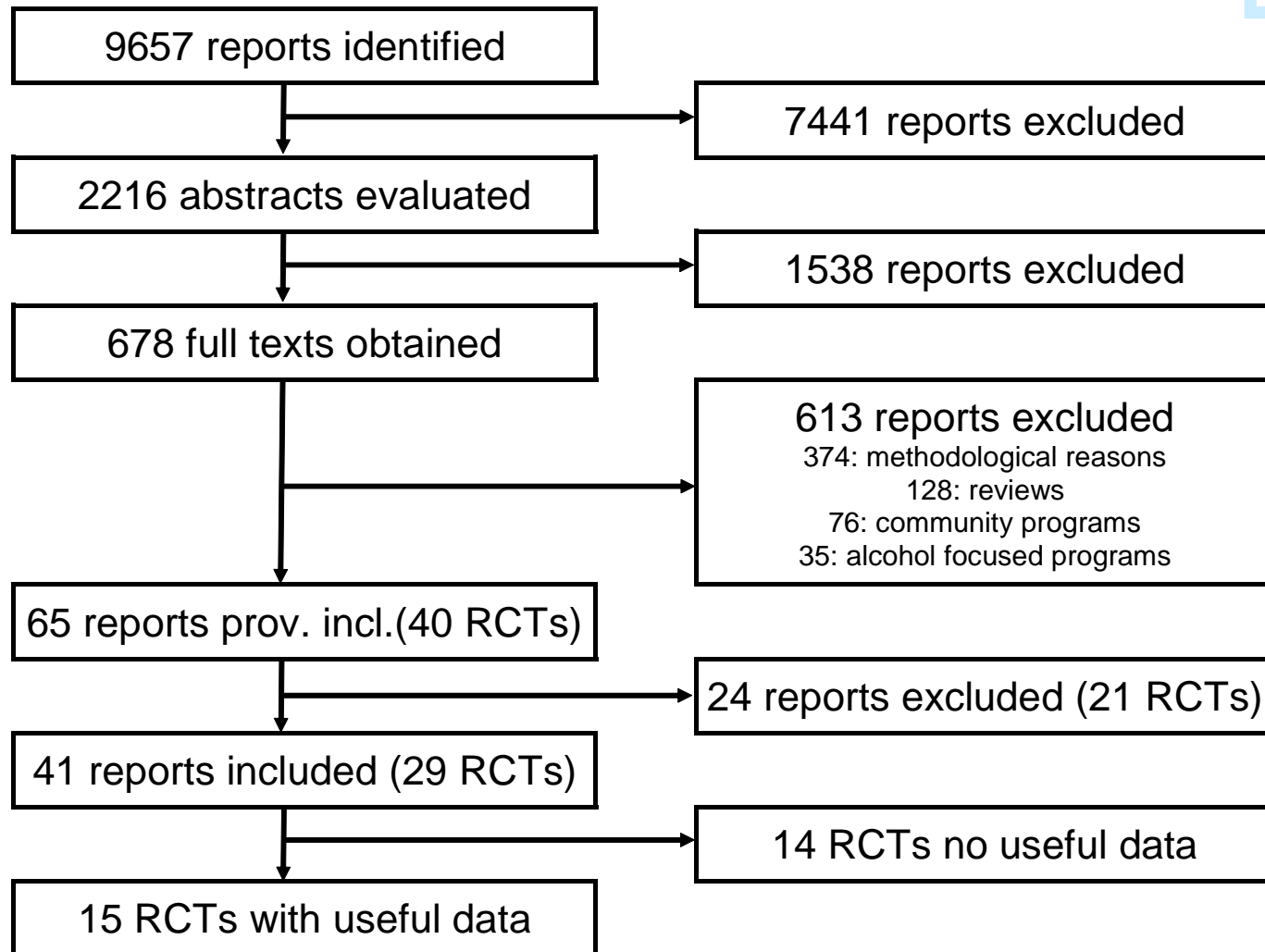




# Flow chart of the review



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# Program classification



The interventions and control arms of the studies were classified as:

- ❖ **skills focused**, aimed to enhance students' abilities in generic, refusal, and safety skills
- ❖ **affective focused**, aimed to modify inner qualities (personality traits such as self-esteem and self-efficacy, and motivational aspects such as the intention to use drugs)
- ❖ **knowledge focused** programs, aimed to enhance knowledge of the effects, and consequences of drug use
- ❖ **usual curricula**

# Included studies



- **29 studies (41 reports)** were included
- 14 did not present data useful for the inclusion in the meta-analyses
- 18 studies were of **6 and 7th grade** students
- in 18 studies the evaluation was based on **post-test** assessment; 13 provided data at 1 year follow-up
- **all but one** were conducted in the **USA**. Only 1 RCT was conducted in the UK





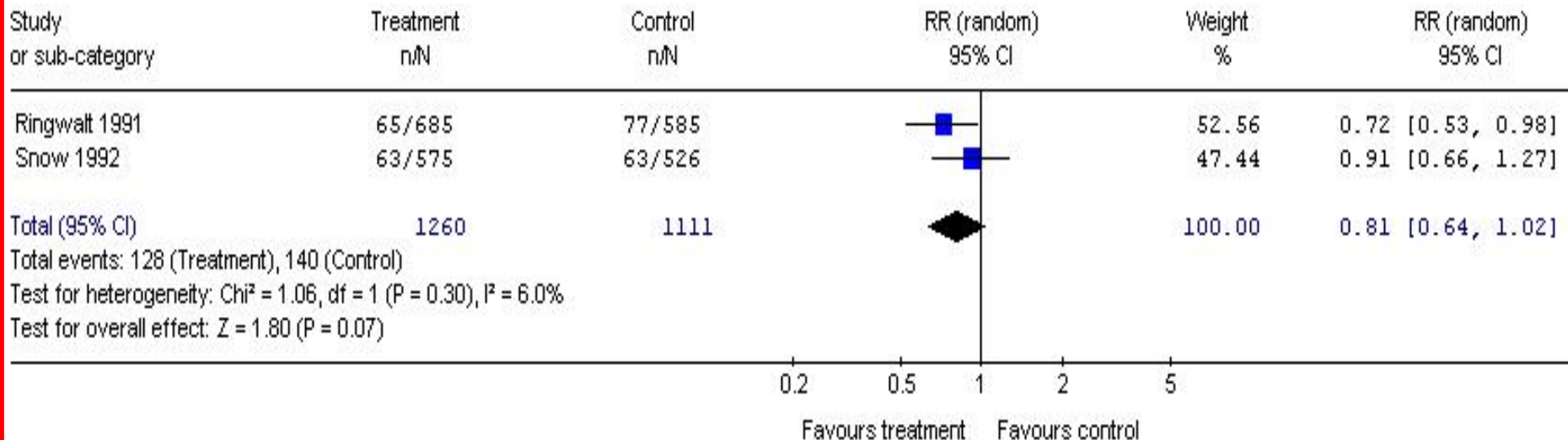
# Results: (I)



**Skills versus usual curricula**  
**drugs use: RR=0.81; CI95%: 0.64, 1.02**

**Reduction: 19%**

Review: School-based prevention for illicit drugs' use.  
Comparison: 02 skills vs usual curricula  
Outcome: 07 drug use





# Results: (II)

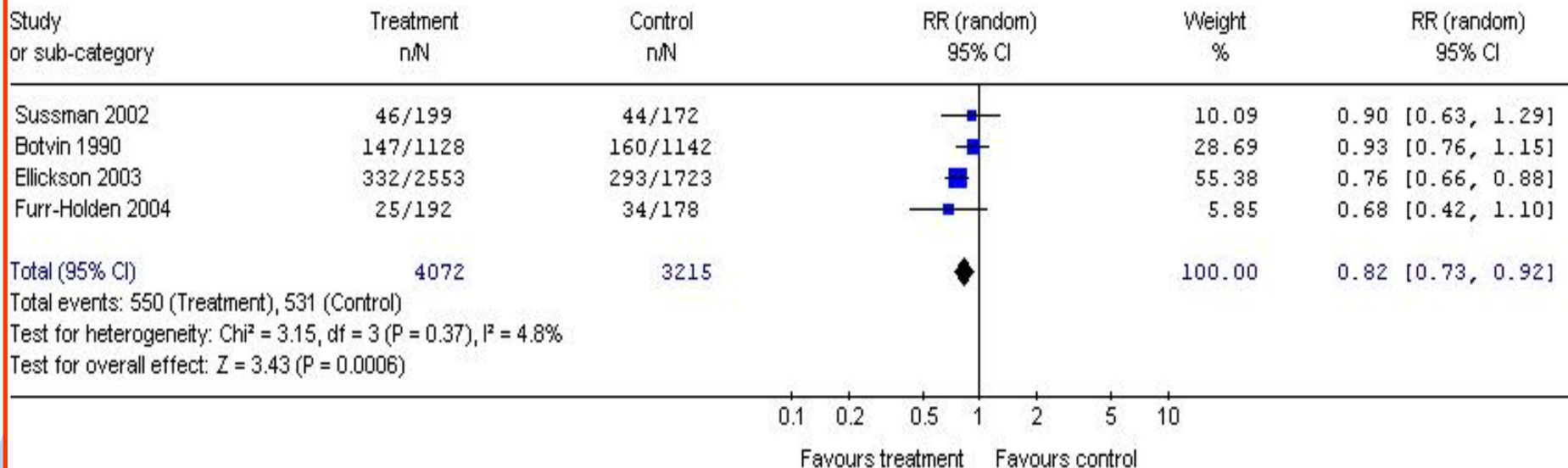


## Skills versus usual curricula

**marijuana use: RR=0.82 CI95%: 0.73, 0.92**

**Reduction: 18%**

Review: School-based prevention for illicit drugs' use.  
Comparison: 02 skills vs usual curricula  
Outcome: 08 marijuana use (all studies)





# Results: (III)

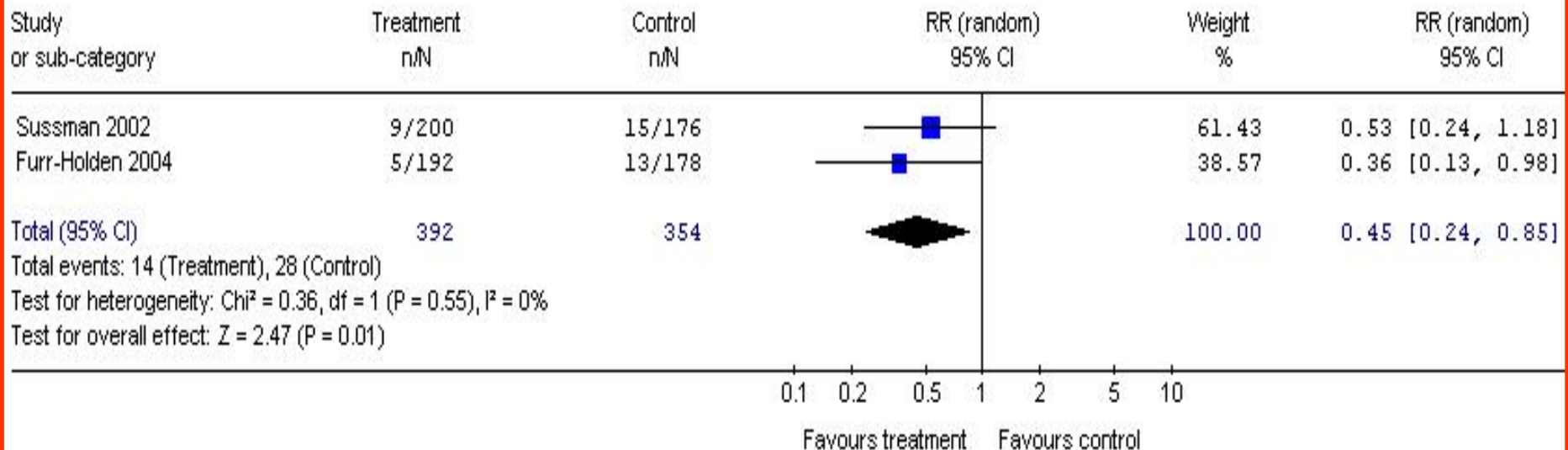


## Skills versus usual curricula

**hard drugs use: RR=0.45; CI95%: 0.24, 0.85**

**Reduction: 55%**

Review: School-based prevention for illicit drugs' use.  
Comparison: 02 skills vs usual curricula  
Outcome: 13 hard drugs use





# Results: (IV)



## Skills versus usual curricula

### Improvement of:

- **drug knowledge:** WMD=2.60 (1.17-4.03)
- **decision making skills:** SMD=0.78 (0.46-1.09)
- **peer pressure resistance:** RR=2.05 (1.24-3.42)
- **self-esteem:** SMD= 0.22 (0.03-0.40)



# Summary of results: (I)



- **Skills focused programs** have a positive effect on both mediating variables and final outcomes, compared to usual curricula
- The meta-analysis on drug and marijuana use showed a **20% lower use** in the intervention groups at the post test, and a 55% lower use of hard drugs
- Most of the RCTs included have a satisfactory methodological quality (mainly quality score=B)



# Summary of results: (II)



- **knowledge focused programs** improve mediating variables (especially **drug knowledge**) compared with usual curricula, but are not more effective than skills based programs
- when final outcomes are considered (drug use), their effects are **comparable to the usual curricula** and the other two types of programs
- **affective-focused programs** improve **decision making skills and drug knowledge** compared to usual curricula and knowledge-focused interventions, but no evidence of effectiveness is shown for use of drugs



# Summary of results: (III)



- **The number needed to treat (NNT=1/ARR) is 33** for marijuana use

Since the prevalence of marijuana use in the post-test of the control arm of the RCTs included in this comparison was **16.5%**

**5 out of 33 students** (16.5% of 33) will use this drug.

Of these, **1 would be prevented** by the intervention, which corresponds to the **20% of the new initiators**



# Limitations



- none of the RCTs satisfied all the **quality criteria**
- most results were outcomes at post test and few data were from **long-term follow-ups**
- many studies did not present effect measures but only statistical indicators so it was impossible to combine them in the meta-analysis
- **measure of effects were very heterogeneous**
- **all but one of the 29 RCTs included were conducted in the USA**





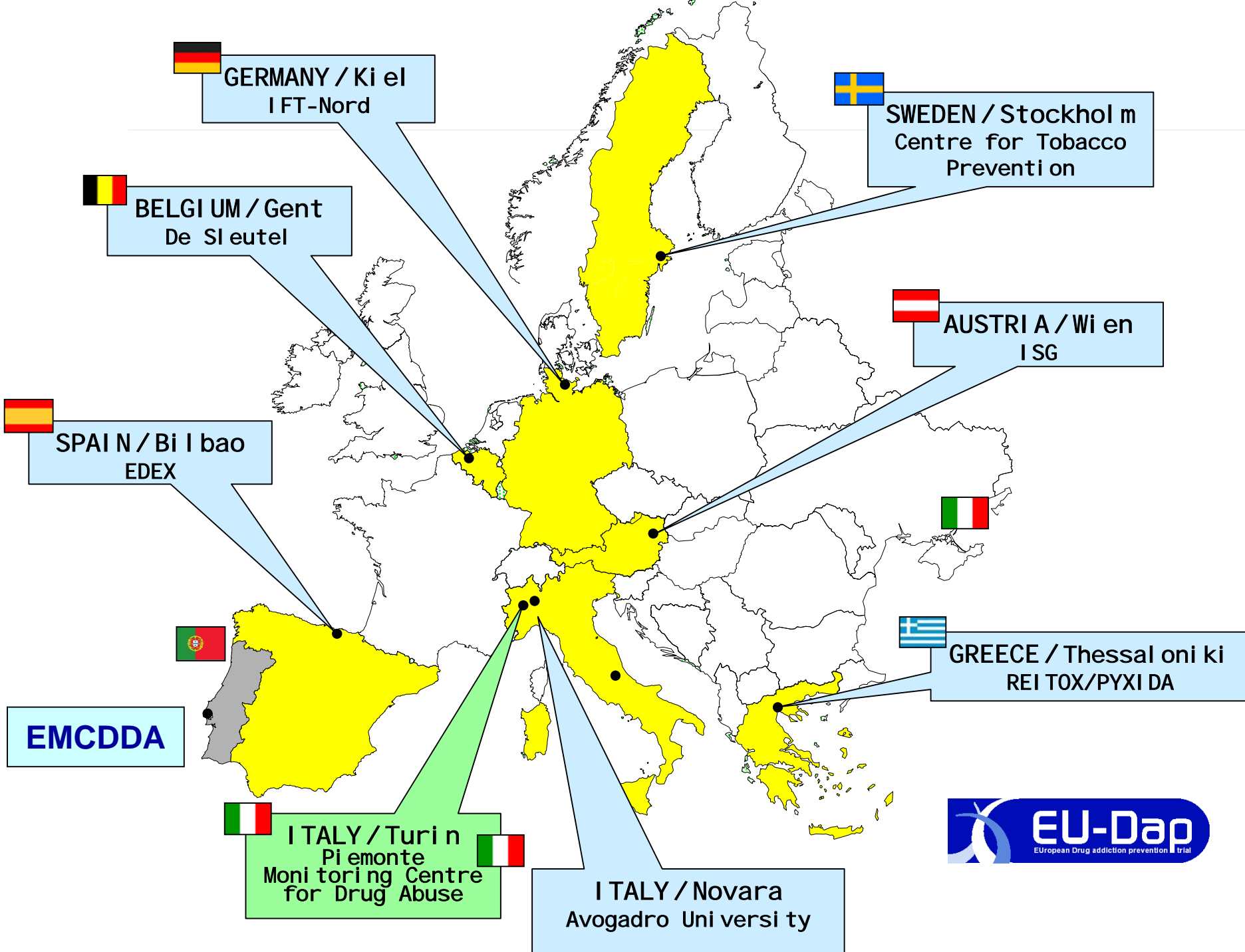
## **EU-Dap study**

**European Drug Addiction  
Prevention trial**



# Characteristics

- ✿ **Experimental study:**
  - Cluster randomized controlled trial
- ✿ **Funded by the European Community**
  - Public Health Program
- ✿ **Involving 9 centers in 7 European Countries**
- ✿ **Conceived by an international expert group**
- ✿ **Supported by EMCDDA**
- ✿ **Main aims:**
  - to build a School-based European Prevention Program (“*Unplugged*”)
  - to evaluate the efficacy of the program





# “Unplugged”

- the program is based on a ***comprehensive social influence approach***
- It includes the following components
  - Social skills
  - Personal skills
  - Knowledge
  - Normative education
  - (No resistance education)
- It is administered by teachers trained in a 3-days course
- It is made by 12 units, 1 hour each





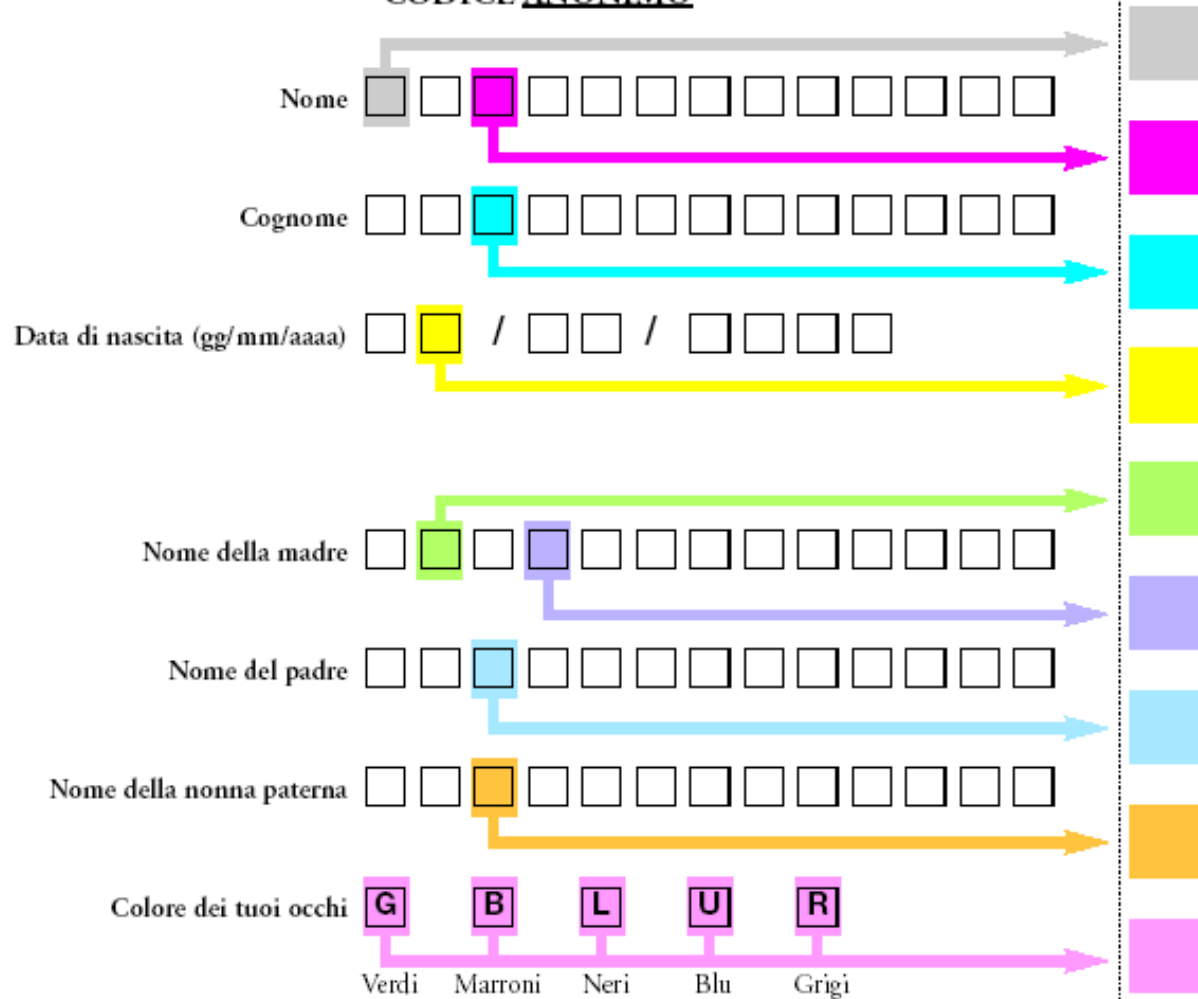
# The 12 units

- **Unit 1:** Opening “Un-plugged”
- **Unit 2:** Choices: risk and protection
- **Unit 3:** Drugs – get informed
- **Unit 4:** Smoking the cigarette – get informed
- **Unit 5:** Your beliefs, norms and information: are they correct?
- **Unit 6:** To be or not to be in a group
- **Unit 7:** Express your self
- **Unit 8:** Party tiger (contacts and non-verbal and verbal ways to present oneself )
- **Unit 9:** Get up stand up (respect for the rights and opinions of the other people)
- **Unit 10:** Coping competence
- **Unit 11:** Problem solving/ decision making
- **Unit 12:** Goal setting and closure

# Individual code



## AUTO-GENERAZIONE DEL CODICE ANONIMO





# The questionnaire



centro scuola classe scuola questionario

**QUESTIONARIO  
su abitudini, usi  
e altre informazioni  
sulle sostanze non alimentari**



# Methods

- EU-Dap is designed as a **Cluster randomised controlled trial**
- The schools to be included were selected **by chance** among all schools of the center area
- A **stratified randomization** has been carried out to ensure a balanced sample according to **social class variables**



# Enrollment

- **7079** students participated in the ***baseline survey*** (November 2004)
- The program ("**Unplugged**") was administered between November 2004 and February 2005 in the intervention arms
- **6604 students** participated in the ***follow-up survey*** (May 2005), at least **3 months** after the end of the program
- The percentage of successful linkage between the baseline and first follow-up questionnaire was **91.5%**

# Enrolled population

	Study Arm					
	Controls		All interventions		Total population	
	(N=3297)		(N=3307)		(N=6604)	
	n	%	n	%	n	%
<b>Centres</b>						
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



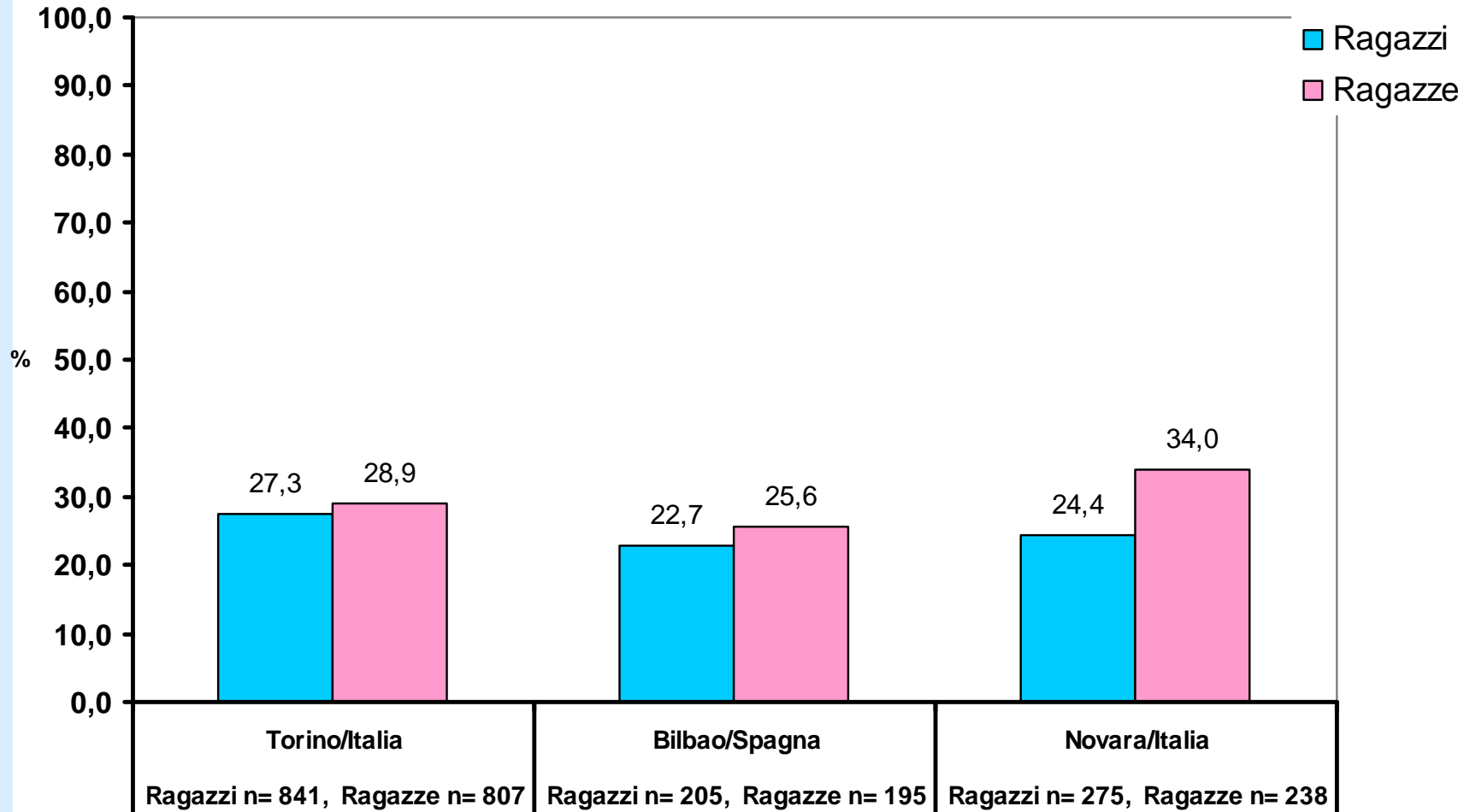
# Differences of use among centers

	ALO smoking	Regular smoking	Daily smoking	ALO drunk	Regular drunk	ALO cannabis	Regular cannabis	ALO drugs
Turin	26.7	17.6	12.0	8.6	2.8	6.9	3.5	9.2
Bilbao	25.0	15.8	9.7	17.3	4.4	13.1	10.4	13.3
Kiel	13.4	7.6	5.0	6.0	2.5	1.4	0.7	3.0
Gent	9.1	4.9	3.1	4.8	1.8	1.9	1.1	6.3
Stockholm	2.9	1.1	0.4	1.9	0.2	0.2	0.1	1.0
Thessaloniki	1.3	0.6	0.4	2.5	1.2	0.7	0.6	2.0
Wien	8.5	4.5	2.4	3.5	0.7	1.3	0.4	2.3
Novara	27.0	14.7	9.1	9.2	1.5	4.2	2.3	5.0
L'Aquila	11.2	4.7	2.5	4.5	1.0	1.0	0.2	1.4



# Smoking cigarettes

I smoked at least one cigarette in the last 30 days

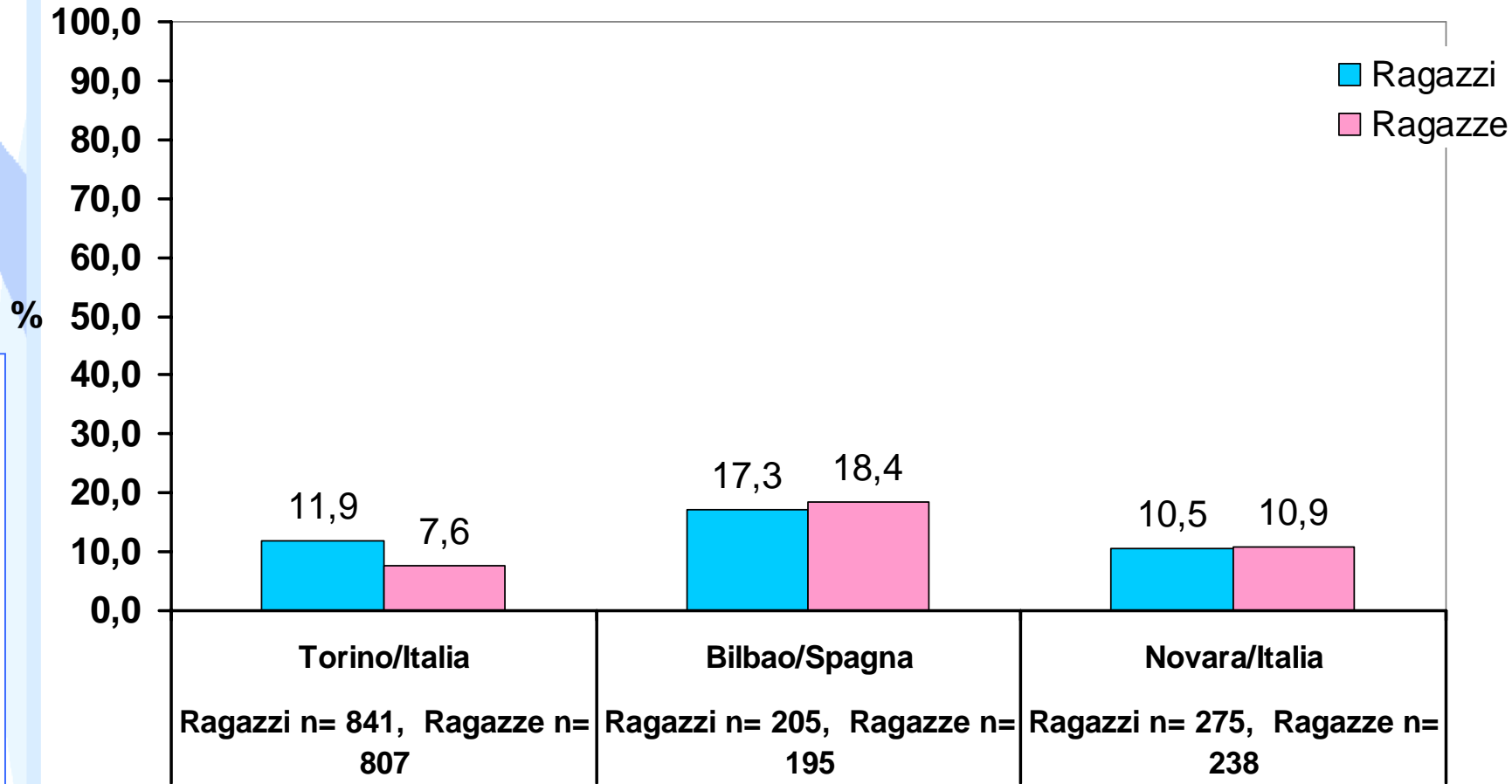






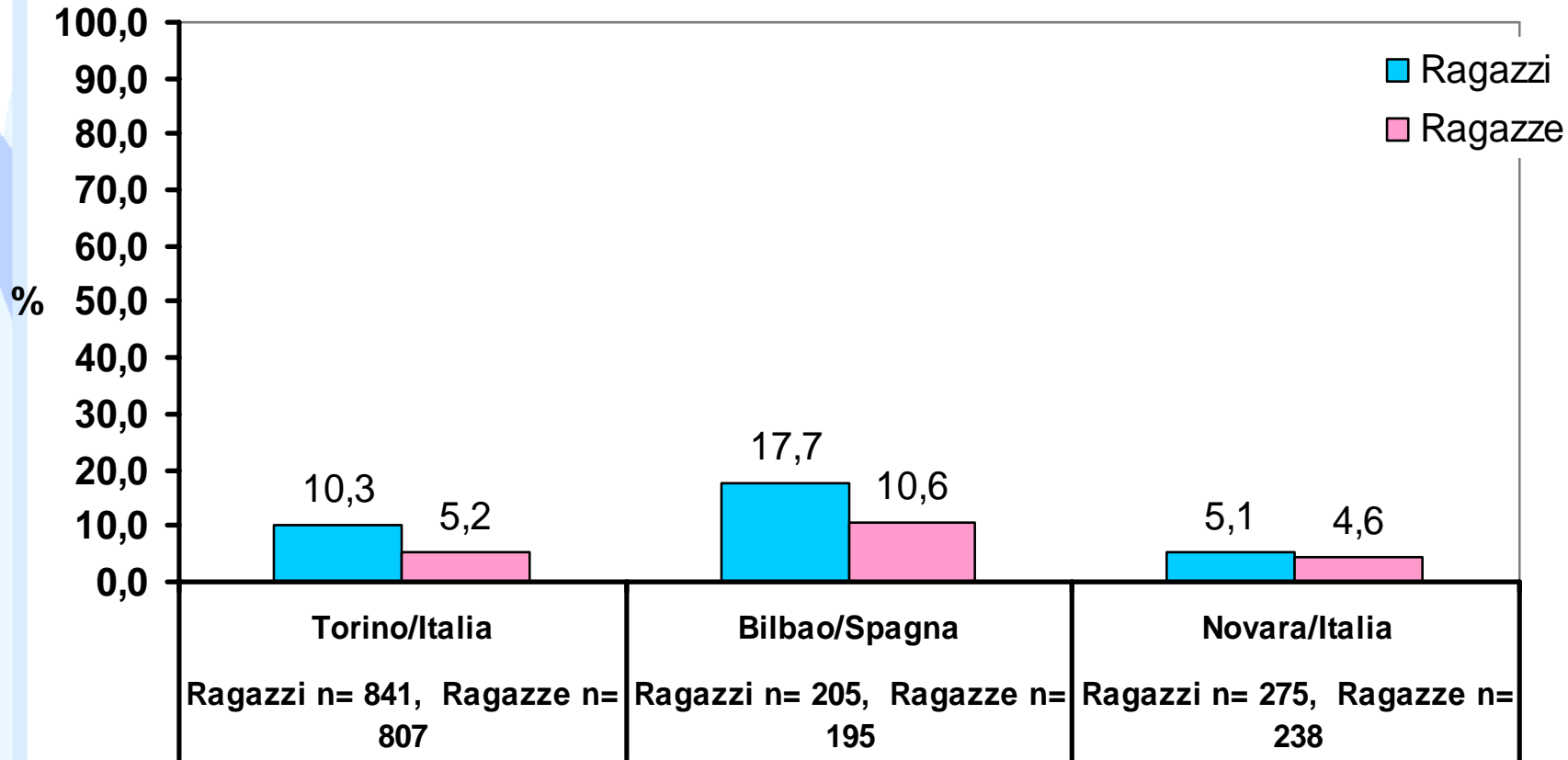
# Have been drunk

I've been drunk at least ONCE in the last 30 days



# Smoking cannabis

I smoked cannabis at least ONCE in the last 30 days

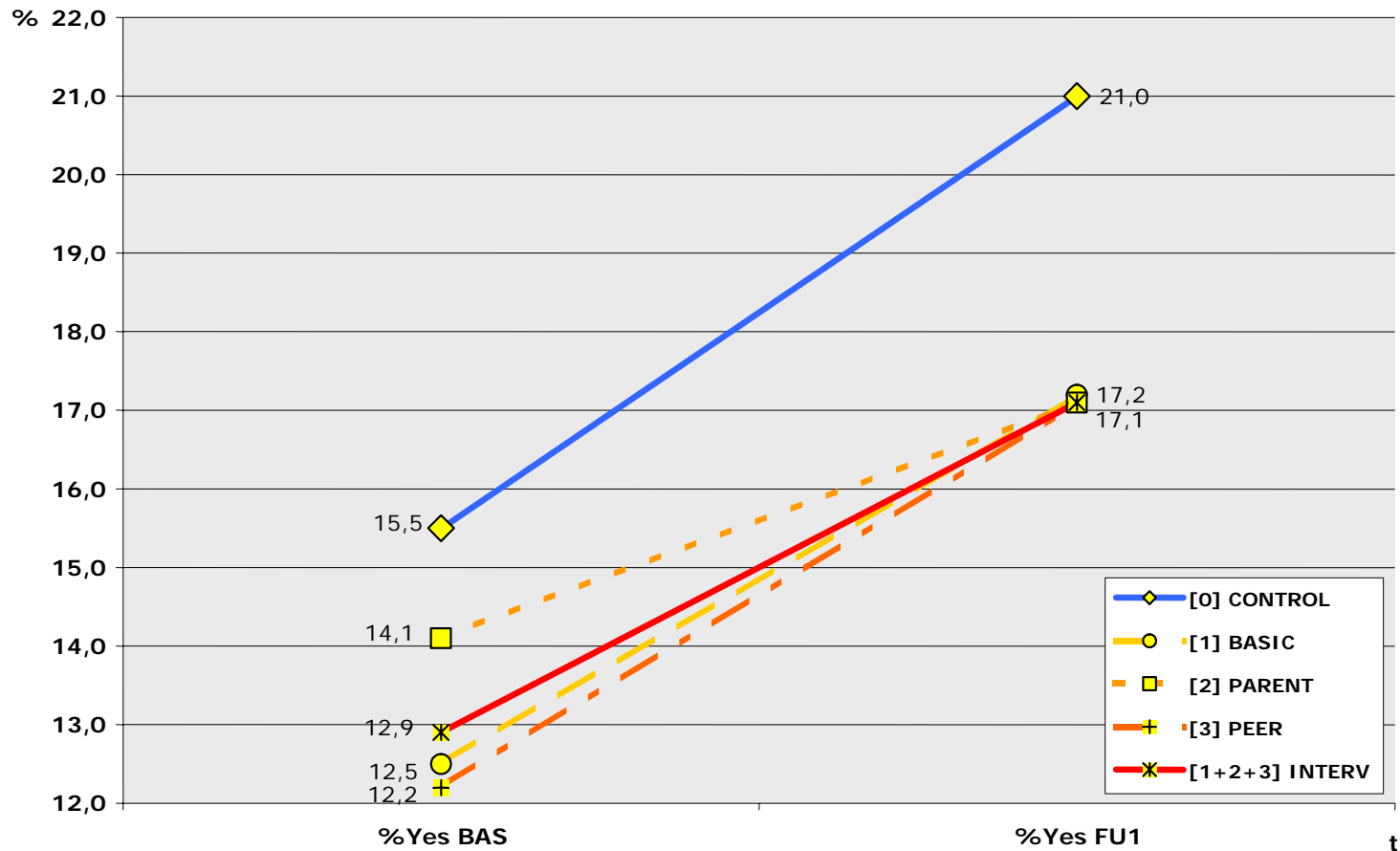




# Measures of effect (last 30 days)

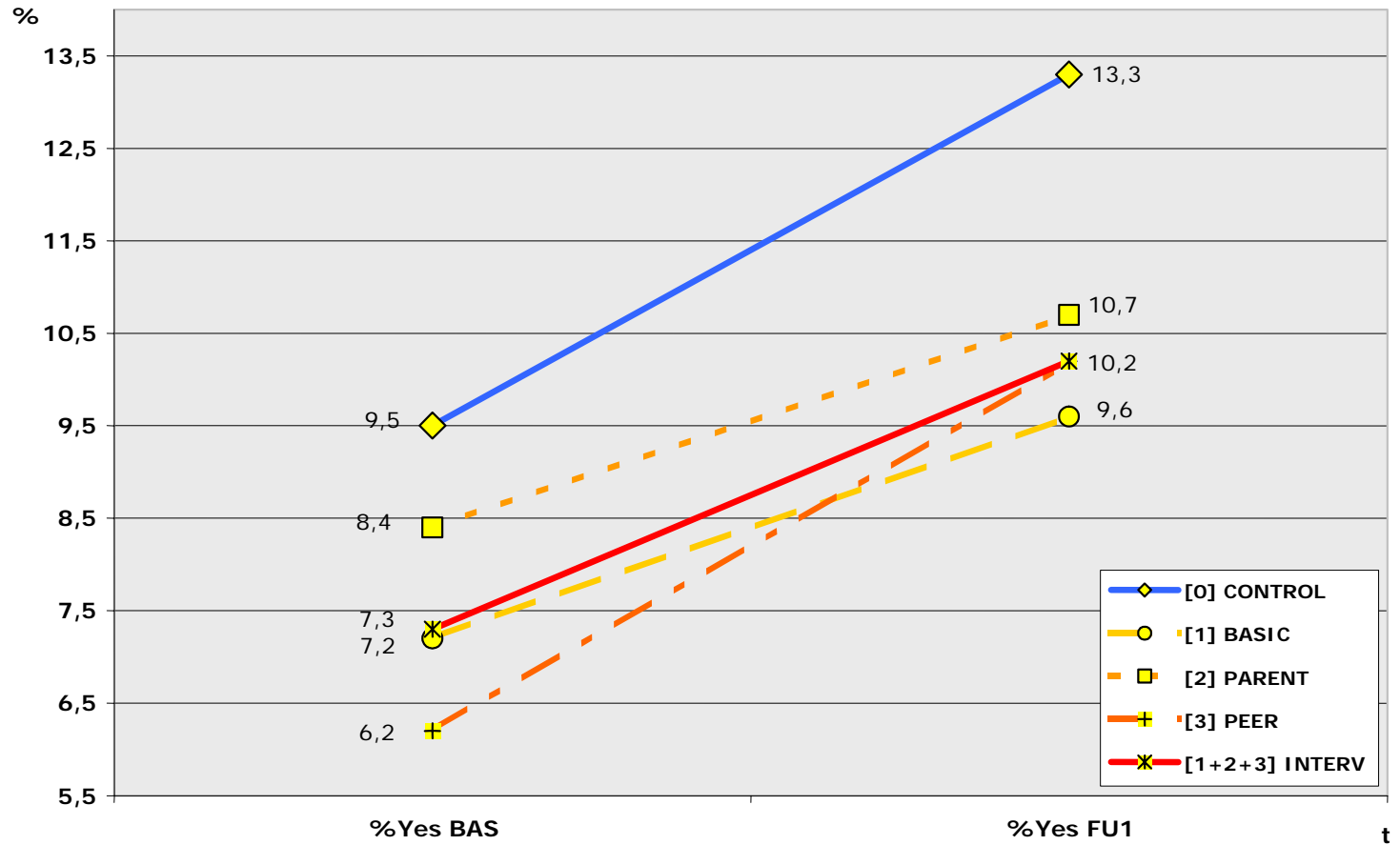
- ***ALO smoking:*** At least once
- ***Regular Smoking:*** At least 6 times
- ***Daily smoking:*** At least 20 times
- ***ALO drunkenness:*** At least once
- ***Regular drunkenness:*** At least 3 times
- ***ALO cannabis:*** At least once
- ***Regular cannabis:*** At least 3 times
- ***ALO drugs:*** At least once (all drugs except cigarettes and alcohol)

# ALO smoking



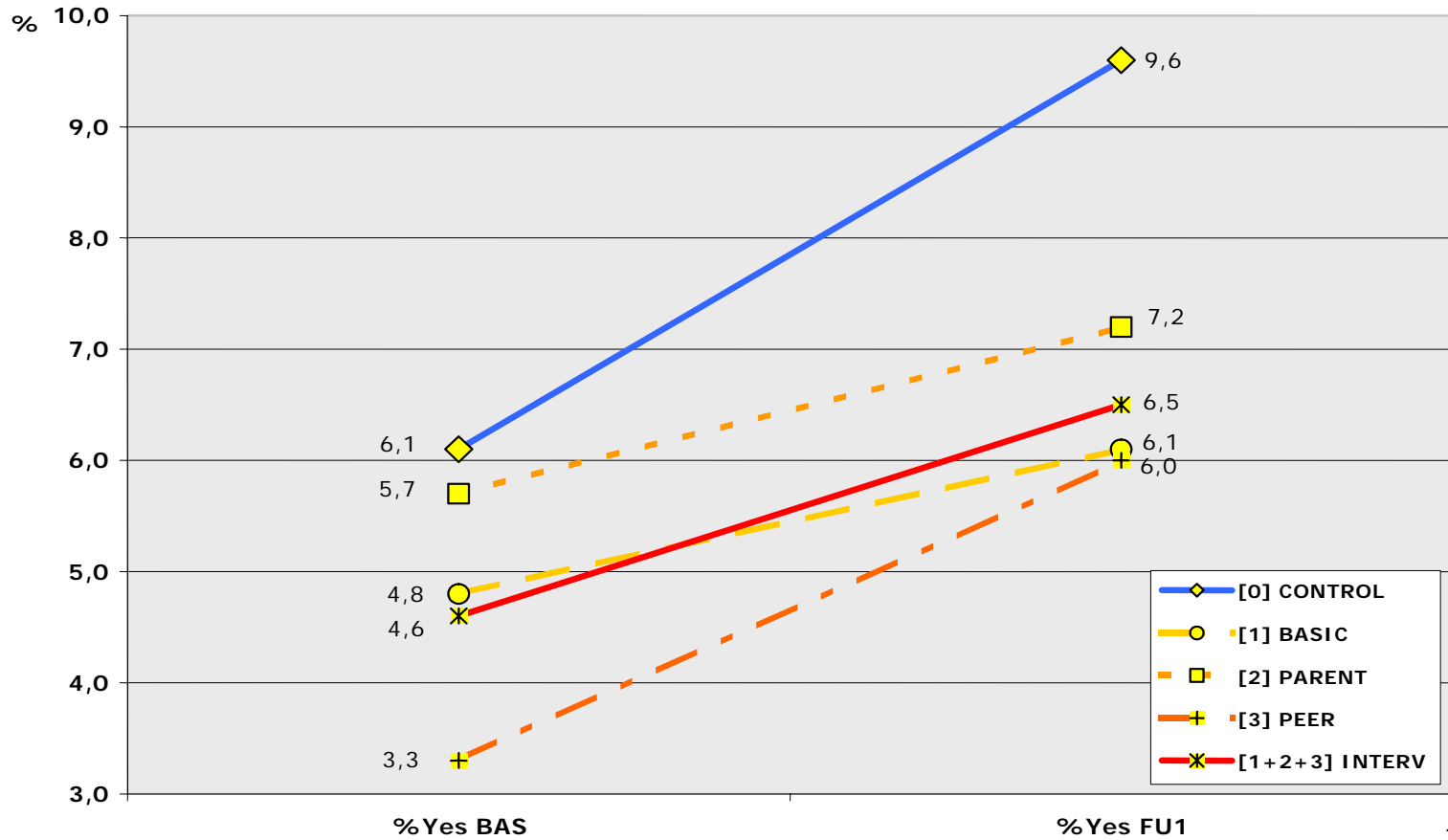


# Regular smoking

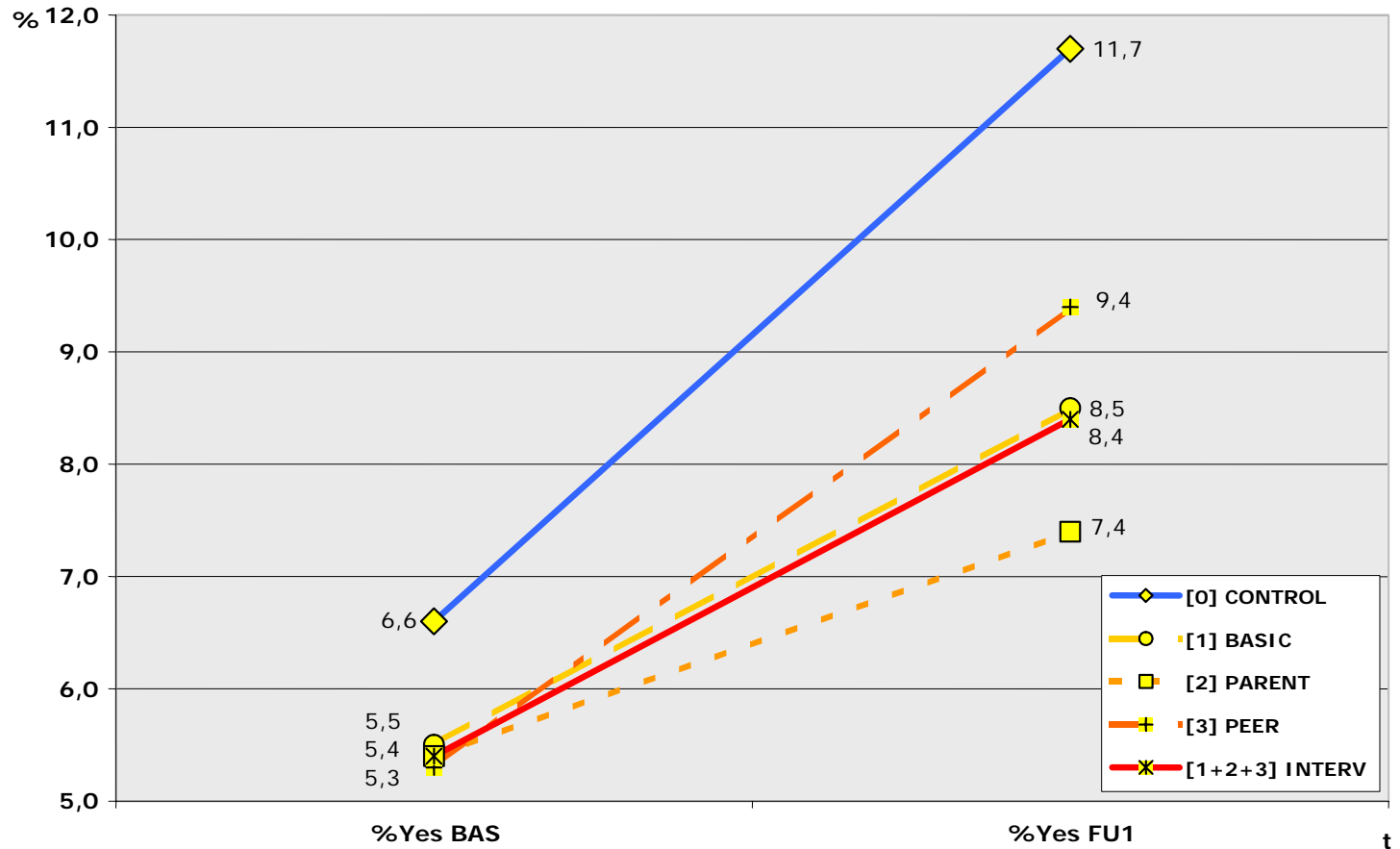




# Daily smoking

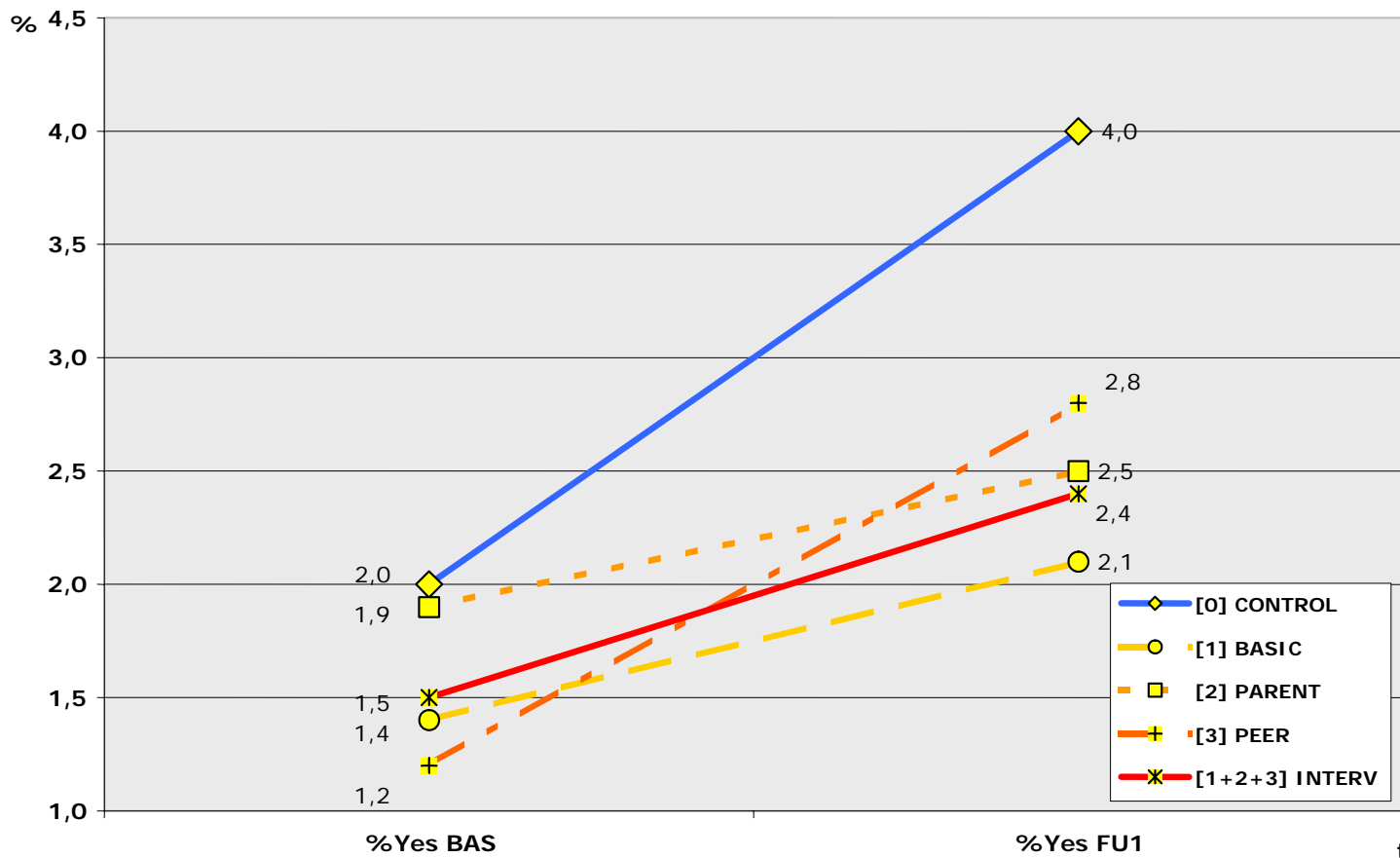


# ALO drunkenness



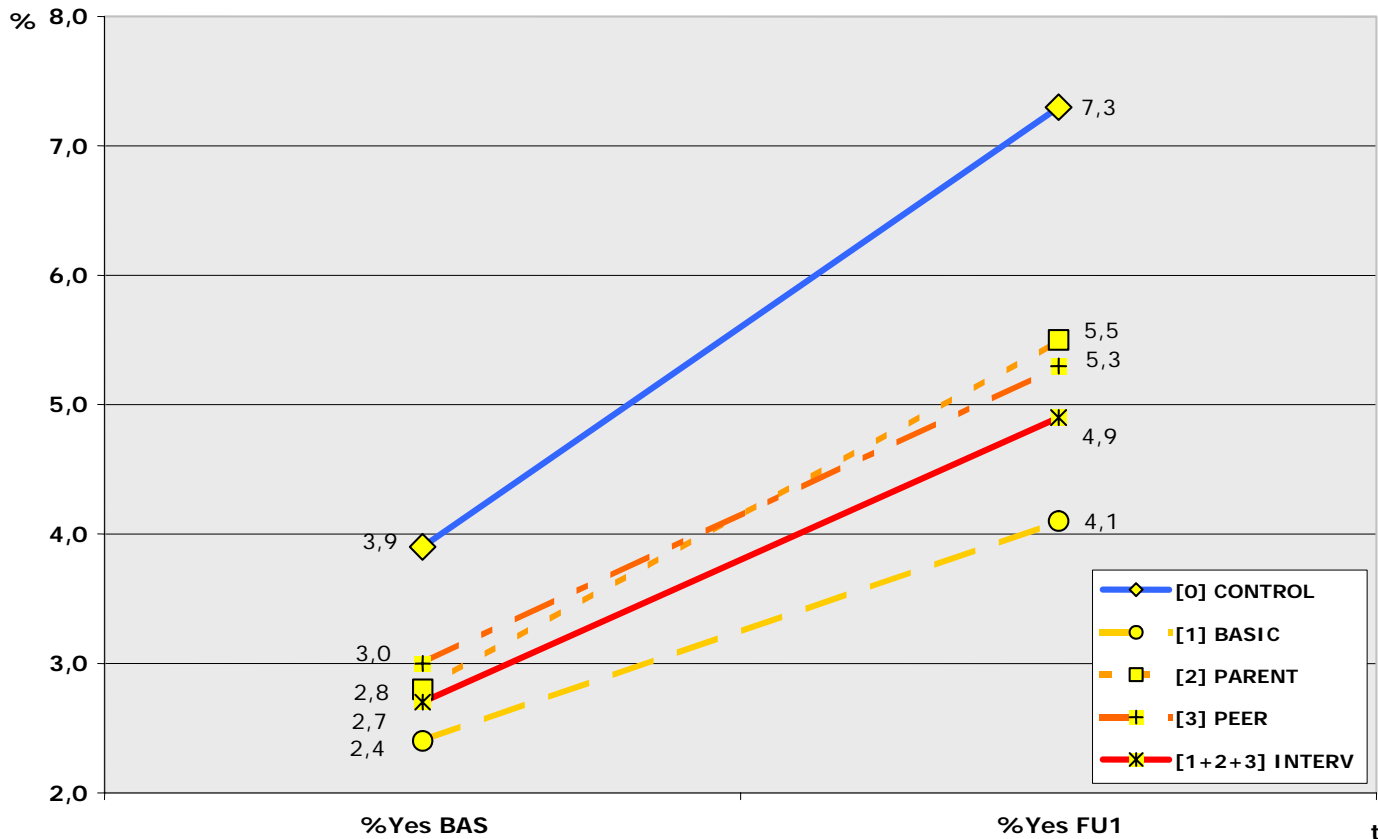


# Regular drunkenness



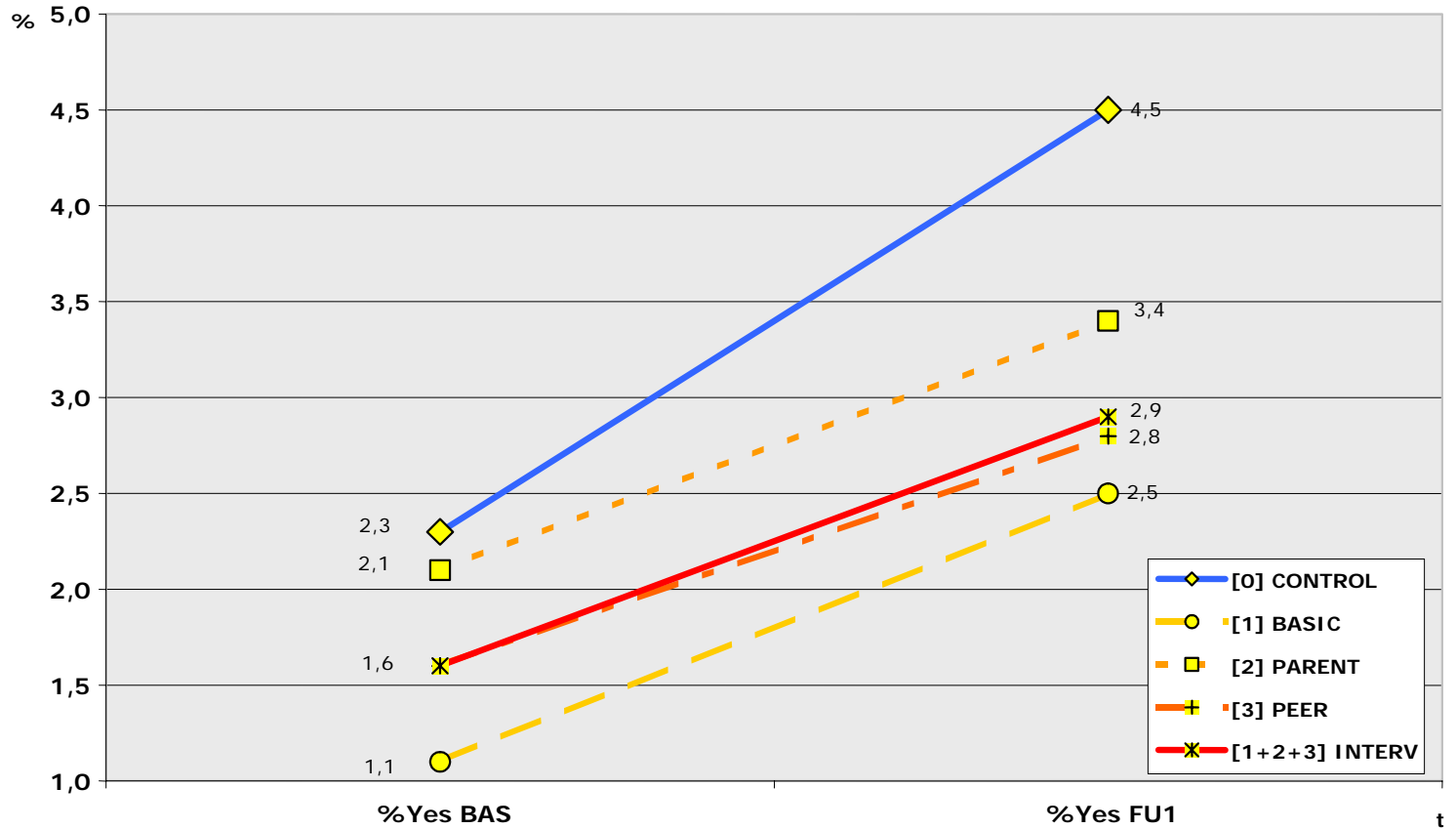


# ALO cannabis





# Regular cannabis





# Adjusted statistical analysis

- A Multi-Level model was used to:
  - Adjust for the ***cluster effect***
  - Take into account the ***differences in the prevalence of use among centers***
  - Take into account the ***differences in the prevalence of use among arms*** (the controls show higher prevalences of use at the baseline)



# Results of the model

	<b>% reduction</b>	<b>CI 95%</b>
<b>ALO smoking</b>	-12%	-29%;+8%
<b>Regular smoking</b>	-14%	-33%;+10%
<b>Daily smoking</b>	<b>-30%</b>	<b>-48%;-6%</b>
<b>ALO drunkenness</b>	<b>-28%</b>	<b>-42%;-10%</b>
<b>Regular drunkenness</b>	<b>-31%</b>	<b>-52%;-1%</b>
<b>ALO cannabis</b>	<b>-23%</b>	<b>-40%;0%</b>
<b>Regular cannabis</b>	-24%	-47%;+9%
<b>ALO drugs</b>	-11%	-31%;+15%

**Model 3: model 2 + adjustment for the baseline status of the outcome**

# Considerations: age

	12 anni		13 anni		14 anni	
	n/N*	%	n/N*	%	n/N*	%
<b>ALO smoking</b>	153/2202	<b>6.9</b>	156/2082	<b>8.5</b>	719/2497	<b>28.8</b>
<b>Regular smoking</b>	85/2202	<b>3.9</b>	85/2082	<b>4.1</b>	477/2497	<b>19.1</b>
<b>Daily smoking</b>	48/2202	<b>2.2</b>	53/2082	<b>2.5</b>	331/2497	<b>13.3</b>
<b>ALO drunkenness</b>	88/2254	<b>3.9</b>	81/2132	<b>3.8</b>	295/2536	<b>11.6</b>
<b>Regular drunkenness</b>	30/2254	<b>1.3</b>	24/2132	<b>1.1</b>	93/2536	<b>3.7</b>
<b>ALO cannabis</b>	30/2273	<b>1.3</b>	21/2154	<b>1.0</b>	217/2576	<b>8.4</b>
<b>Regular cannabis</b>	16/2273	<b>0.7</b>	9/2154	<b>0.4</b>	136/2576	<b>5.3</b>
<b>ALO drugs</b>	76/2289	<b>3.3</b>	39/2170	<b>1.8</b>	267/2594	<b>10.3</b>

**14 years old students have very high level of use**





# Considerations: peers and parents

	Study arm			
	Ctrl	Basic	Parents	Peers
	POR	POR (95%CI)	POR (95%CI)	POR (95%CI)
ALO smoking	1	0.97 (0.71-1.33)	0.80 (0.59-1.09)	0.89 (0.65-1.21)
Regular smoking	1	0.81 (0.56-1.19)	0.85 (0.59-1.24)	0.90 (0.64-1.27)
Daily smoking	1	0.64 (0.41-1.01)	0.72 (0.47-1.12)	0.75 (0.49-1.16)
ALO drunk..	1	0.79 (0.57-1.09)	0.61 (0.44-0.85)	0.82 (0.60-1.12)
Regular drunk..	1	0.66 (0.37-1.19)	0.67 (0.40-1.13)	0.76 (0.47-1.24)
ALO cannabis	1	0.79 (0.54-1.16)	0.76 (0.53-1.09)	0.79 (0.54-1.16)
Regular cannabis	1	0.83 (0.47-1.45)	0.75 (0.45-1.25)	0.75 (0.44-1.28)
ALO drugs	1	0.80 (0.56-1.15)	0.98 (0.69-1.38)	0.89 (0.64-1.25)

**The involvement of parents and peers do no change the results**

**the basic intervention works better**



# Considerations: parents smoking

**% of students who smoked cigarettes at least once according to the smoking status of parents and siblings**

	<b>Parents Not Smoking</b> (N=3042)	<b>One Parent Smoking</b> (N=2396)	<b>Both Parents Smoking</b> (N=1554)	<b>Siblings Not Smoking</b> (N=4847)	<b>Siblings Smoking</b> (N=1276)	<b>Total</b> (N=7079)
<b>%</b>	<b>28.3</b>	<b>38.2</b>	<b>43.1</b>	<b>28.0</b>	<b>59.1</b>	<b>35.0</b>
<b>N</b>	857	910	663	1348	744	2442



# Considerations: parents permission

**% of students who smoked cigarettes or have been drunk at least once according to the parents' permission**

		<b>Would allow</b>	<b>Wouldn't allow</b>	<b>Don't know</b>	<b>Total</b>
		(N=1091)	(N=5169)	(N=690)	(N=7079)
<b>ALO smoked cigarettes</b>	<b>%</b>	<b>61.0</b>	<b>29.3</b>	<b>36.8</b>	<b>35.1</b>
	<b>N</b>	663	1506	251	2420
		(N=1463)	(N=4108)	(N=1334)	(N=7079)
<b>ALO drunkenness</b>	<b>%</b>	<b>43.8</b>	<b>16.6</b>	<b>26.0</b>	<b>24.2</b>
	<b>N</b>	640	680	345	1665





# Conclusions: (I)

- The statistical analysis shows that **Unplugged** is effective in reducing use of drugs, alcohol and cigarettes at the first follow-up
- it seems to work better:
  - for high frequent users than for sporadic ones
  - for boys than for girls
- there are **large differences between centers** (data not shown) that are explained by **differences in the implementation of the program**
- the lack of effect of any extra intervention (parents, peers) have to be explained, yet



# Conclusions: (II)

- It is the *first european program* evaluated through a multicentric, randomized controlled trial design
- the **follow-up at 1 year** will give data to test the stability over time of the results

**Thank you for the attention and..  
Keep in touch with EU-Dap!!!**

**[www.eudap.net](http://www.eudap.net)**