European Drug Prevention Trial (EU-DAP)
Life skills training evaluation results

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Background

- School is an appropriate setting for drugs use prevention programs
- In European countries virtually all schools carry out interventions to prevent the onset of substance use
  - most are theory-based, some aren't
  - most have been evaluated only for intermediate variables (knowledge, intentions…)
  - but the evaluation of effectiveness in reducing the use of drugs is very rare
- There is a solid suspicion that some programmes can make harm (Dukes 1997; Hawthorne 1996)

"Life education" program's evaluation

Cigarette smoking: RR=1.60
Alcohol use: RR=1.40
Other substances use RR=1.40

When the data are extrapolated to the state-wide smoking and drinking estimates, these showed that of all smoking among year 6 schollchildren, 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 program was extended to all Australia, UK, USA, … India, China, … South Africa….

….The findings suggest that intervention programmes should be thoroughly evaluated prior to widespread implementation…

Hawthorne 1995

Background

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

Focuses of this presentation

1. **Cochrane Review on *School-based prevention for illicit drugs' use*** (Faggiano, 2005)
2. final results of **EU-Dap trial**

Systematic review

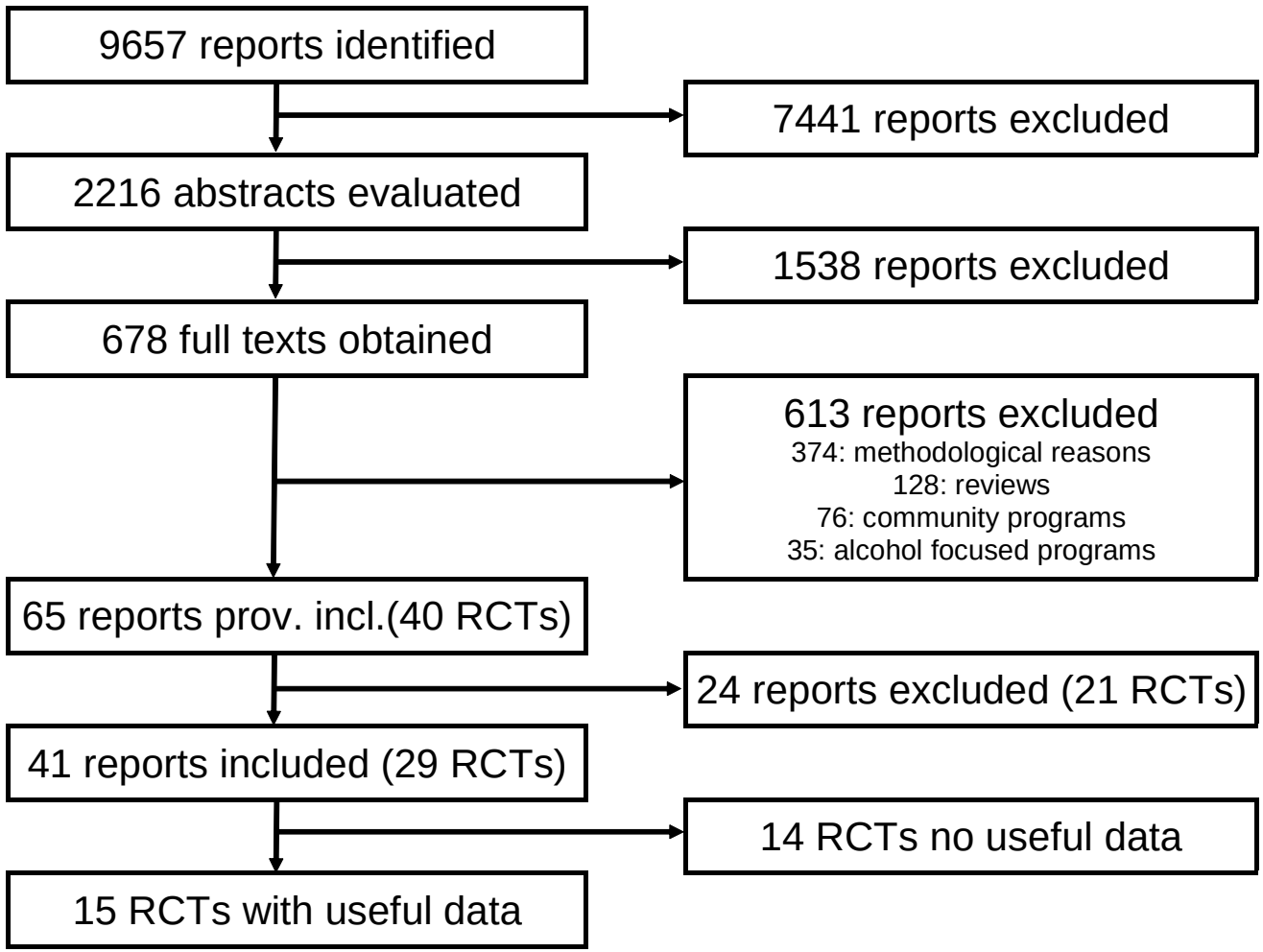
- ***Systematic review*** is a methodology developed by the ***Evidence Based Medicine*** to summarise the results of scientific studies
- The ***Cochrane Collaboration*** is the international no-profit network aimed at developing systematic reviews on effectiveness of health technologies using standardised methodologies
- Cochrane Library (www.cochrane.org)

Methods

Literature search and inclusion criteria

- All RCTs and CPS (Controlled Prospective Studies) evaluating any intervention program versus a control condition
- The following databases have been searched (from beginning to feb 2004)
  - Medline & Embase
  - ERIC, Sociological Abstracts, Psychinfo
  - Cochrane databases
- To discover unpublished researches/results, research teams, and 18 authors of studies were contacted

Flow-chart of considered studies



Methods

Data collection and extraction

- For the 29 RCTs included, interventions and control arms 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 and the effects, and consequences of drug use
  - ***usual curricula***

Results

Included studies

- 29 studies (41 reports) were included
- 14 did not present data for inclusion in the meta-analyses (limited reporting from statistical models)
- 18 studies were of 6th and 7th grade students

- 18 studies presented a post-test assessment;
- 13 provided data at 1 year follow-up.
- Few studies provided data for longer periods

- 28/29 were conducted in the USA (1 RCT in the UK)

Results

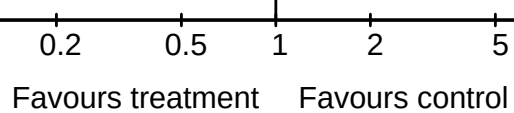
Skills versus usual curricula

The only comparison showing significant results are skills vs usual curricula

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

Study or sub-category	Treatment n/N	Control n/N	RR (random) 95% CI	Weight %	RR (random) 95% CI
Ringwalt 1991	65/685	77/585		52.56	0.72 [0.53, 0.98]
Snow 1992	63/575	63/526		47.44	0.91 [0.66, 1.27]
Total (95% CI)	1260	1111		100.00	0.81 [0.64, 1.02]

Total events: 128 (Treatment), 140 (Control)
Test for heterogeneity: Chi² = 1.06, df = 1 (P = 0.30), I² = 6.0%
Test for overall effect: Z = 1.80 (P = 0.07)



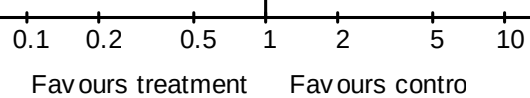
Results

Skills versus usual curricula

Review: School-based prevention for illicit drugs' use. (Vs first published 2/200
Comparison: 02 skills vs usual curricula
Outcome: 13 hard drugs use

Study or sub-category	Treatment n/N	Control n/N	RR (random) 95% CI	Weight %	RR (random 95% CI
Sussman 2002	9/200	15/176		61.43	0.53 [0.24, 1.18]
Furr-Holden 2004	5/192	13/178		38.57	0.36 [0.13, 0.98]
Total (95% CI)	392	354		100.00	0.45 [0.24, 0.85]

Total events: 14 (Treatment), 28 (Control)
Test for heterogeneity: Chi² = 0.36, df = 1 (P = 0.55), I² = 0
Test for overall effect: Z = 2.47 (P = 0.0



Results

Skills versus usual curricula

Review: School-based prevention for illicit drugs' use. (Vs first published 2/200

Comparison: 02 skills vs usual curricula

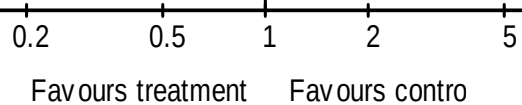
Outcome: 08 marijuana use (all studies)

Study or sub-category	Treatment n/N	Control n/N	RR (random) 95% CI	Weight %	RR (rando 95% CI
Sussman 2002	46/199	44/172		10.09	0.90 [0.63, 1.29]
Botvin 1990	147/1128	160/1142		28.69	0.93 [0.76, 1.15]
Ellickson 2003	332/2553	293/1723		55.38	0.76 [0.66, 0.88]
Furr-Holden 2004	25/192	34/178		5.85	0.68 [0.42, 1.10]
Total (95% CI)	4072	3215		100.00	0.82 [0.73, 0.92]

Total events: 550 (Treatment), 531 (Control)

Test for heterogeneity: Chi² = 3.15, df = 3 (P = 0.37), I² = 4.8

Test for overall effect: Z = 3.43 (P = 0.000



Results

Skills versus usual curricula

- Skills based intervention reduced
  - drug use (RR=0.81 => -19%)
  - hard drug use (RR=0.45 => -55%)
  - marijuana use (RR=0.82 => -18%)

- Improvement in intermediate variables
  - drug knowledge (WMD=2.60; CI95%: 1.17, 4.03)
  - decision making skills (SMD=0.78; CI95%: 0.46, 1.09)
  - peer pressure resistance (RR=2.05; CI95%: 1.24, 3.42)
  - self-esteem (SMD= 0.22; CI95%: 0.03, 0.40)

Other results

- Other interventions
  - No significant differences were found comparing other programmes with usual curricula
  - neither in comparisons between programmes

- peer involvement
  - no final outcomes have been used by studies comparing peer involvement vs control

First conclusion

- Number needed to treat (NNT; 1/ARR) is 33 for marijuana use

- Since the prevalence of marijuana among controls was 16.5%, 5 out of 33 students (16.5% of 33) will use this drug.
- Of this, 1 would be prevented by the intervention

So the intervention should be able to obtain a 20% reduction of the new initiators

General considerations

- The wide variability of indicators, scales and scores employed, and the limited reporting of data make ***results very heterogeneous***
- The ***quality*** of research is ***generally low*** (out of 50 selected RCTs, only 29 were included)
- There is a major concern on ***generalisability***: 28/29 RCTs included were conducted in the USA
- Authors stated for a need of ***further corroboration*** of results by well designed, long term follow-up, cluster-randomised trials, especially in countries other than the USA

The EU-Dap Study

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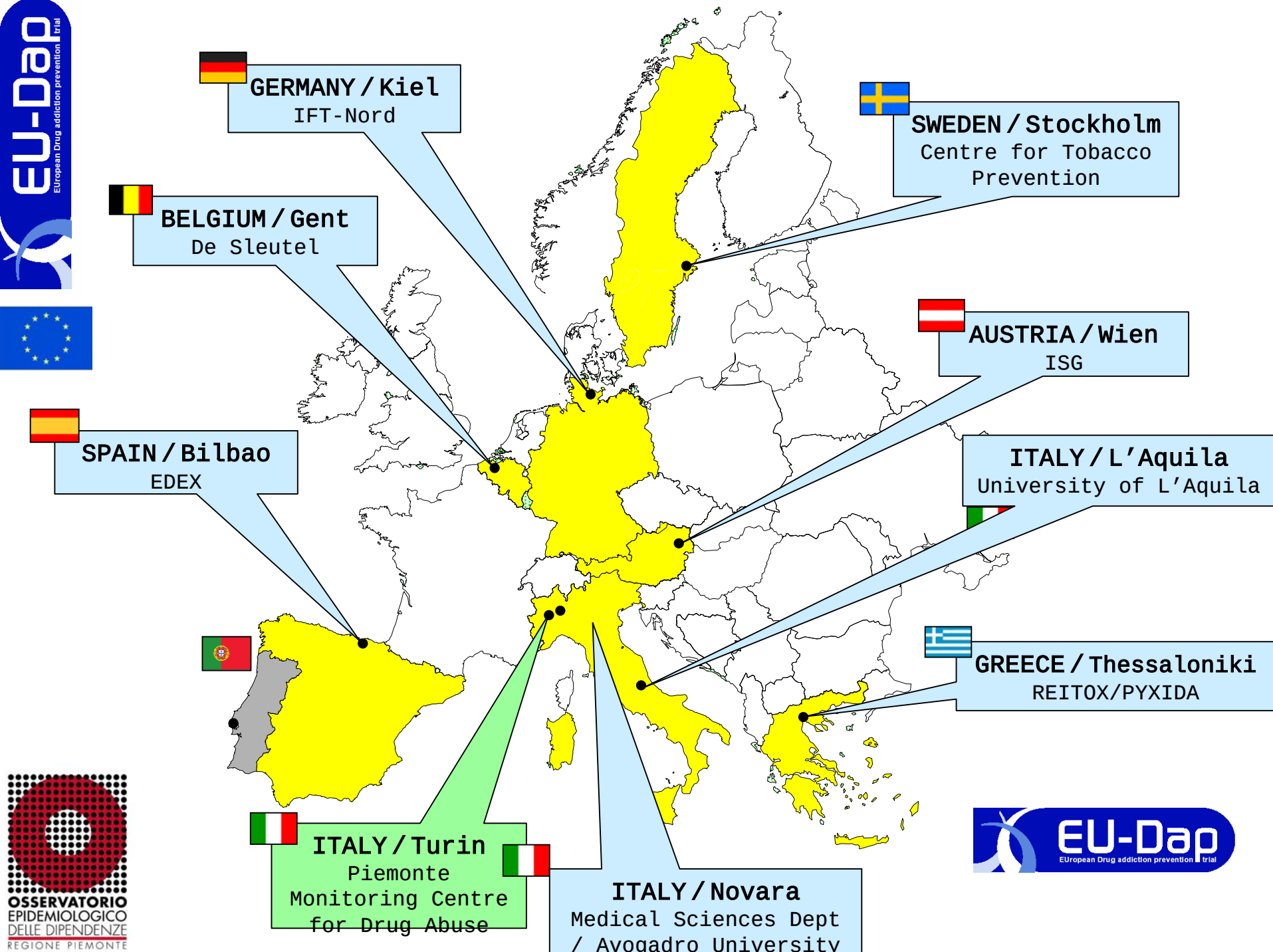
The EU-Dap Study

- 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
SWEDEN / Stockholm
Centre for Tobacco Prevention
BELGIUM / Gent
De Sleutel
AUSTRIA / Wien
ISG
SPAIN / Bilbao
EDEX
ITALY / L'Aquila
University of L'Aquila
GREECE / Thessaloniki
REITOX/PYXIDA
ITALY / Turin
Piemonte Monitoring Centre for Drug Abuse
ITALY / Novara
Medical Sciences Dept / Avogadro University
EU-Dap
EUropean Drug addiction prevention trial
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The program "Unplugged"

- A prevention program based on a ***comprehensive social influence approach***
- including the following components:
  - Social skills
  - Personal skills
  - Knowledge
  - Normative education
  - (No resistance education)
- delivered by the class teachers, trained with a 3-days training course
- 12 one-hour units delivered weekly from October 2004 to January 2005

Study design

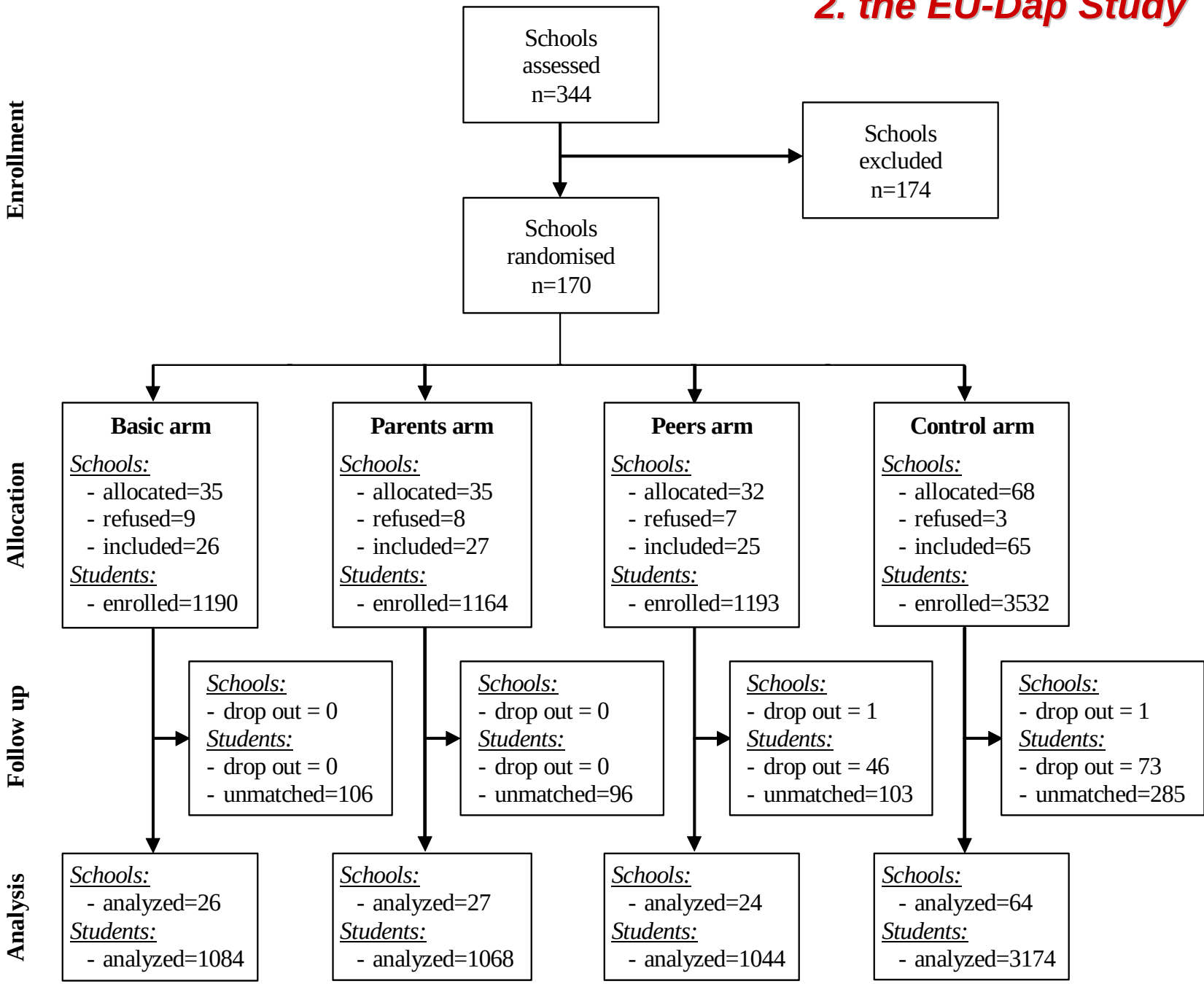
- The aim of "***Unplugged***" is to prevent or delay the onset of tobacco and drugs use, and of alcohol misuse

- To evaluate his effectiveness EU-Dap is a ***Cluster randomised controlled trial***
- The schools to be included has been selected by chance among all schools of the centre area
- A stratified randomisation has been carried out to ensure a balanced sample according to social class variables

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

2. the EU-Dap Study



Questionnaire

- Self completed ***anonymous*** questionnaire on use of substances, attitudes, and other information

- linkage between pre- and post-test by a ***self generated code*** based on fixed data (some letters from name of parents, date of birth..)

- to be repeated for long term follow-up

Baseline-followup matching

- 6370 out of 7079 (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
  - the last step was a manual linkage, carried independently by 2 researchers, at the level of class

Baseline prevalence of use by gender

		Boy (N=3680)	Girl (N=3288)	Total (N=7079)
ALO smoked cigarettes	%	14.2	16.9	15.5
	N	497	537	1034
	N	218	208	426
ALO drunkenness	%	7.3	6.0	6.7
	N	260	194	454
	N	83	57	140
ALO smoked cannabis	%	4.7	2.8	3.8
	N	169	92	261
	N	110	47	157
ALO drugs use	%	6.1	4.6	5.4
	N	223	150	373

Effect of the parent's smoking on children's behaviour

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

Effect of the parent's permission to smoke or to be drunk

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

Characteritics of the analysis sample

	Study Arm					
	Controls (N=3297)		All interventions (N=3307)		Total population (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

Characteritics of the analysis sample

	Study Arm					
	Controls (N=3297)		All interventions (N=3307)		Total population (N=6604)	
	n	%	n	%	n	%
School Grade						
7th level	1469	46.3	1499	46.9	2968	46.6
8th level	425	13.4	634	19.8	1059	16.6
9th level	1280	40.3	1063	33.3	2343	36.8

Characteritics of the analysis sample

	Study Arm					
	Controls (N=3297)		All interventions (N=3307)		Total population (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

Effect measure: prevalence

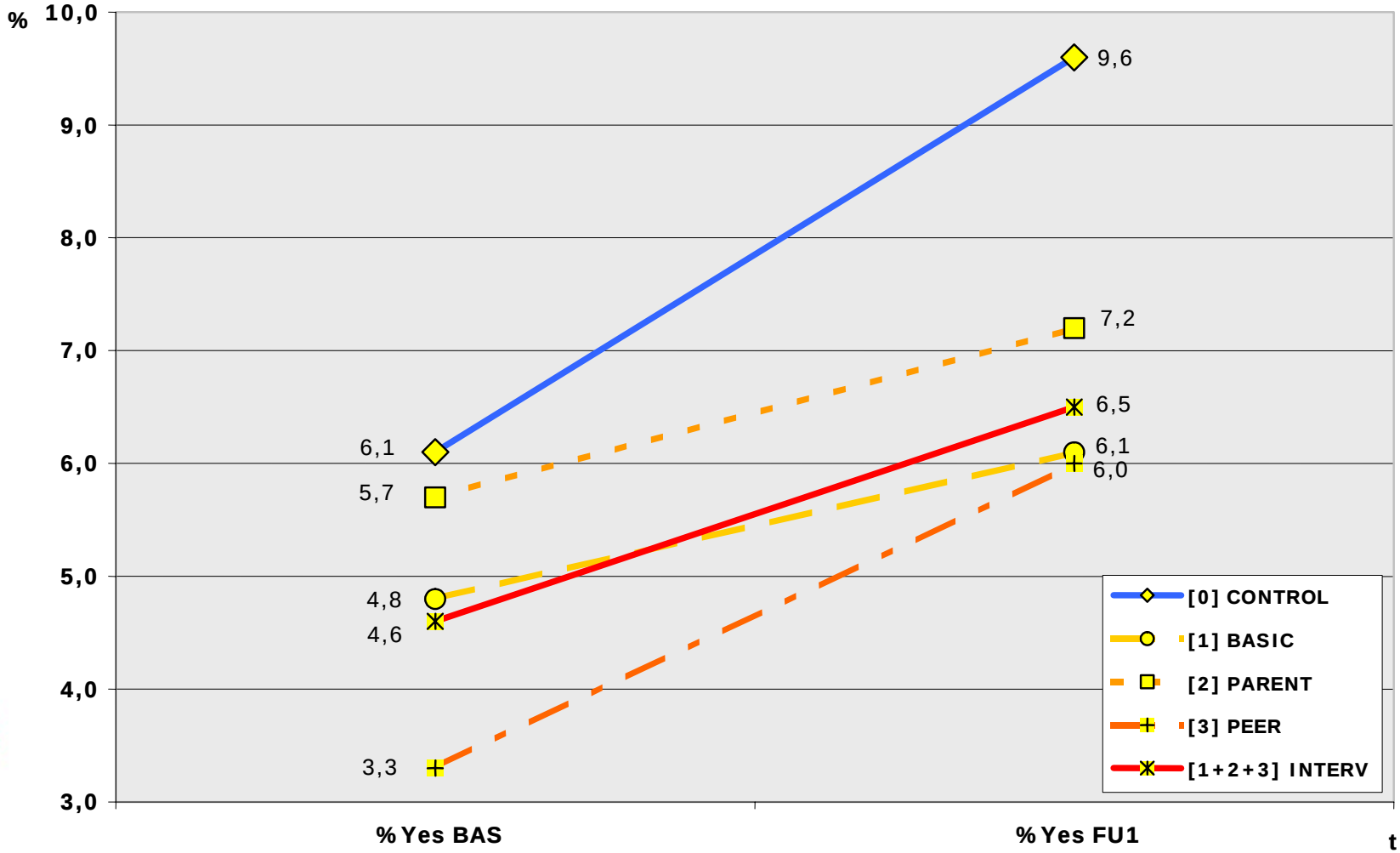
- Because of a baseline imbalance between intervention and control groups, the prevalence at the follow-up could not be use without adjustment
- We decide to control the baseline imbalance through the regression model

Outcomes measures

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

Changes in prevalence of smoking

(daily smoking in last 30 days)



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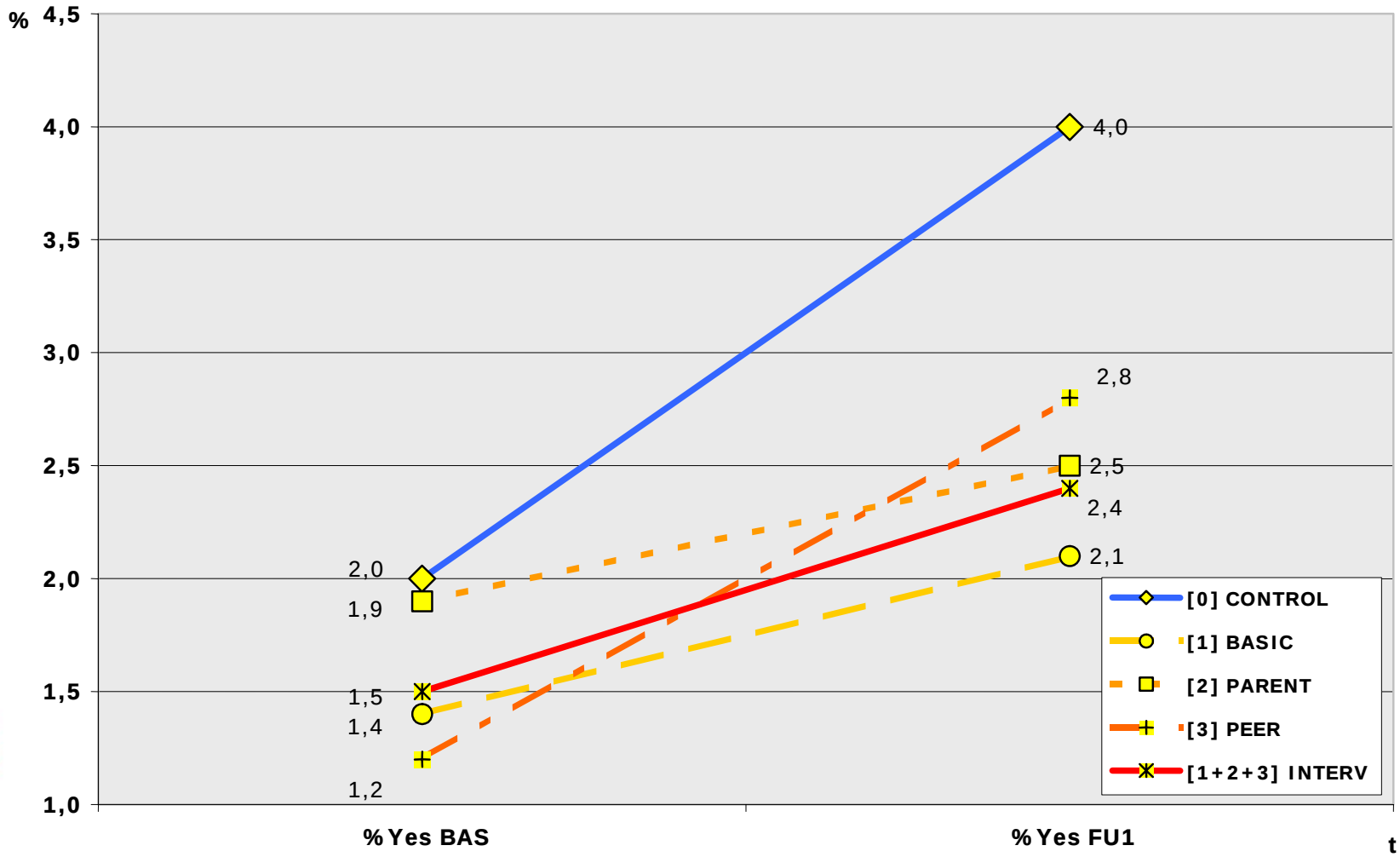
Changes in prevalence of drunkenness
(regular drunkenness in last 30 days)



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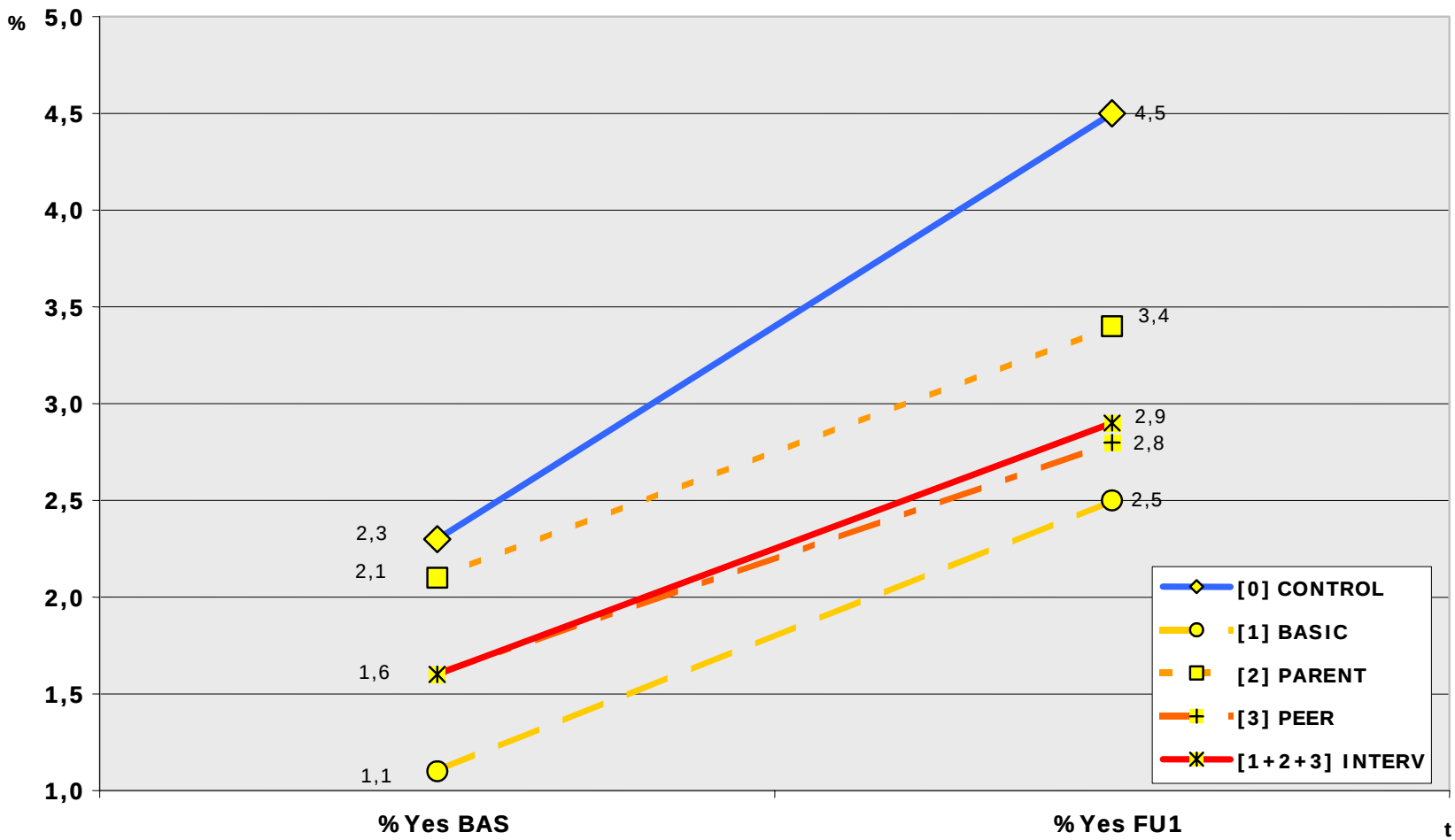
Changes in prevalence of use of cannabis
(regular use in last 30 days)



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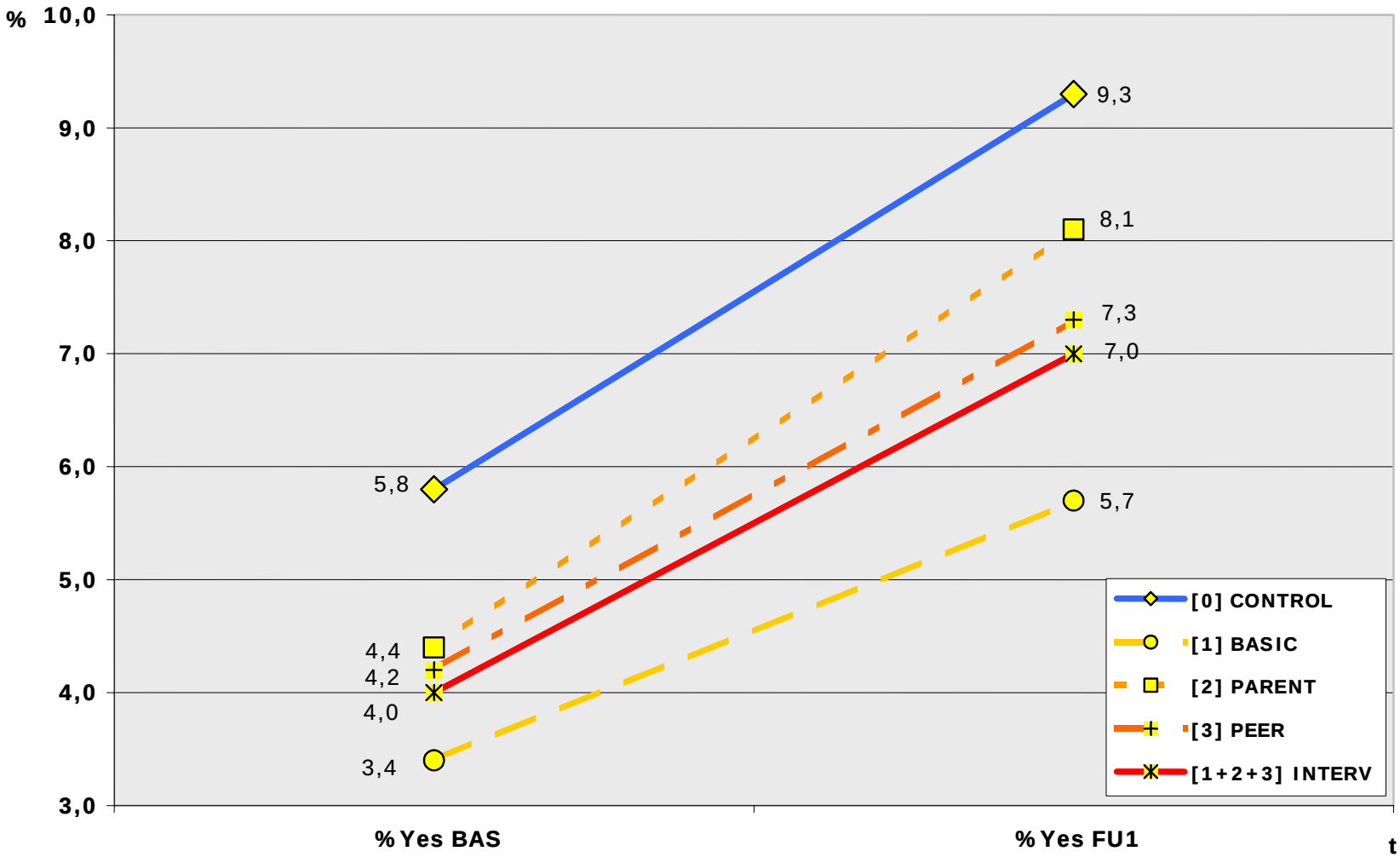
Changes in prevalence of use of drugs

(ALO in last 30 days)



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Some preliminary considerations

- There are very small (and statistically non significant) differences among the study arms
- Even if the ***basic intervention*** appears to work better
- For power considerations, the following analysis will be done grouping together interventions

Prevalence of use
(not adjusted for the cluster effect)

	Controls				All interventions						
	All subjects	users F-U	Prev	PR	all subjects	users F-U	Prev	PR	95%CI	p	APR
ALO smoked cigarettes	3059	642	0.210	1	3098	531	0.171	0.82	0.74-0.91	<0.0005	0.03
Daily use	3059	294	0.096	1	3098	200	0.065	0.67	0.57-0.80	<0.0005	0.04
Regular use	3059	407	0.133	1	3098	315	0.102	0.76	0.67-0.88	<0.0005	0.03
ALO drunkenness	3112	363	0.117	1	3145	265	0.084	0.72	0.62-0.84	<0.0005	0.03
Regular	3112	123	0.040	1	3145	77	0.024	0.62	0.47-0.82	<0.005	0.02
ALO smoked cannabis	3157	230	0.073	1	3179	157	0.049	0.68	0.56-0.83	<0.0005	0.02
Regular use	3157	141	0.045	1	3179	92	0.029	0.65	0.50-0.84	<0.005	0.02
All drugs use	3171	294	0.093	1	3191	224	0.070	0.76	0.64-0.89	<0.005	0.02

Incidence of use
(not adjusted for the cluster effect)

	Control				All interventions						
	not users BAS	new users F-U	Inc	RR	not users BAS	new users F-U	Inc	RR	95%CI	p	AIR
ALO smoked cigarettes	2516	247	0.098	1	2597	224	0.086	0.88	0.74-1.04	NS	0.01
Daily use	2786	128	0.046	1	2842	76	0.027	0.58	0.44-0.77	<0.001	0.02
Regular use	2687	158	0.059	1	2766	126	0.046	0.77	0.62-0.97	<0.05	0.01
ALO drunkenness	2857	233	0.082	1	2920	174	0.060	0.73	0.60-0.88	<0.005	0.02
Regular	2995	90	0.030	1	3038	58	0.019	0.64	0.46-0.88	<0.01	0.01
ALO smoked cannabis	3008	132	0.044	1	3066	93	0.030	0.69	0.53-0.90	<0.01	0.01
Regular use	3061	81	0.026	1	3101	57	0.018	0.69	0.50-0.97	<0.05	0.01
All drugs use	2972	181	0.061	1	3059	151	0.049	0.81	0.66-1.00	<0.05	0.01

Adjusted analysis

- There are 2 major reasons for adjustment:

1. The control for the ***cluster effect*** (to correct the ***inflated precision*** due to the lower ***intraclass variability***)
2. To correct for the ***imbalance in the baseline characteristics*** (controls have higher prevalences)

Adjusted analysis

- The ***Multilevel Regression Model*** (also called Random Effect Model) is considered the best model for the analysis of ***Cluster RCTs***, and allows for the control of imbalance too
- We decided to use ***Daily smoking*** (as fixed effect) to control for imbalance, because it appears to be a more stable variable

Multilevel analysis

Regression model with 3 levels (center class student)
prevalence of daily smoking at the level of centre
as fixed effect

outcome	all		
	N ctrl	N int	OR (95%CI)
ALO smoking	642/3059	531/3098	0.88 (0.71-1.08)
Regular smoking	407/3059	315/3098	0.85 (0.65-1.10)
Daily smoking	294/3059	200/3098	**0.74 (0.55-0.99)**
ALO drunkenness	363/3112	265/3145	**0.74 (0.60-0.92)**
Regular drunkenness	123/3112	77/3145	**0.65 (0.46-0.92)**
ALO cannabis	230/3157	157/3179	**0.77 (0.61-0.98)**
Regular cannabis	141/3157	92/3179	0.77 (0.57-1.03)
ALO drugs	294/3171	224/3191	0.85 (0.67-1.09)

Multilevel analysis

Regression model with 3 levels (center class student)
prevalence of daily smoking at the level of centre
as fixed effect

outcome	males			females		
	N cntr	N int	OR (95%CI)	N cntr	N int	OR (95%CI)
ALO smoking	327/1566	236/1634	0.77 (0.60-1.00)	314/1487	295/1460	0.97 (0.73-1.30)
regular smoking	222/1566	133/1634	**0.65 (0.48-0.87)**	184/1487	182/1460	0.93 (0.64-1.36)
daily smoking	167/1566	83/1634	**0.56 (0.40-0.78)**	126/1487	117/1460	0.89 (0.58-1.36)
ALO drunkenness	214/1588	145/1661	**0.69 (0.53-0.90)**	148/1519	120/1480	0.83 (0.62-1.11)
regular drunkenness	83/1588	51/1661	**0.66 (0.44-0.98)**	39/1519	26/1480	0.66 (0.39-1.12)
ALO cannabis	165/1617	91/1686	**0.59 (0.45-0.79)**	64/1534	66/1489	0.91 (0.65-1.28)
regular cannabis	109/1617	56/1686	**0.57 (0.40-0.80)**	31/1534	36/1489	0.78 (0.47-1.31)
ALO drugs	195/1627	116/1691	**0.63 (0.48-0.83)**	97/1537	108/1496	0.77 (0.55-1.09)

Discussion of results

- ***Unplugged*** works, a least in a 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

Critical points

- there are big ***differences between centers*** (a North-South gradient - data not shown) that seems to be explained by differences in the implementation of the program and by the interventions involving control schools
- the ***lack of effect*** of any extra intervention (***parents, peers***) have to be explained, yet
- the follow-up at 1 year will give data to test the stability over time of the results

Next steps

- the ***final report*** and the ***main scientific paper*** are in preparation
- the ***Intervention Manual*** will be published soon with some recommendations of use

- The EU Commission approved Eu-Dap 2:
  - continuation of the follow-up
  - 2° Intervention Manual release based on performance analysis and comments of teachers
  - production of an Implementation Manual, giving recommendations to policy makers and school authorities on the way to diffuse the programme

A final consideration and a few questions

- "***Unplugged***" is the only school prevention programme proven to be effective against tobacco and drugs use and alcohol abuse
- Are similar programs as effective than "***Unplugged***"?
- How to ***disseminate*** the program across EU schools?
- How can EU-Dap contribute to a virtuous action of ***Evidence-based Policy Making***?

The EU-Dap Group

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