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Evaluation in substance abuse prevention

Federica Vigna-Taglianti

**Regional Centre for Drugs Abuse Epidemiology
OED Piemonte, Torino - ITALY**



Difficulties of the evaluation

- **Levels of evaluation**
- **Subjects responsible for evaluation**
- **Tools for evaluations**
- **cost/benefit of evaluations**
- **Study design**
- **Study conduction**
- **Interpretation of results**
- **Communication**

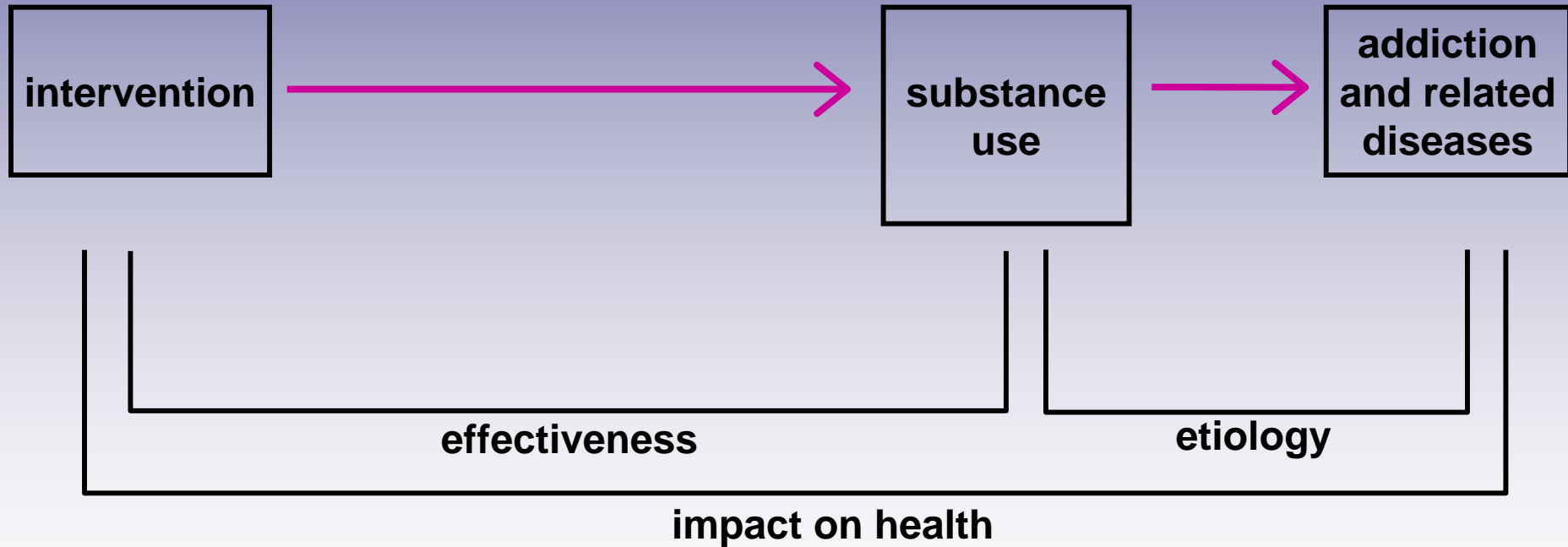
Levels of evaluation in substance use prevention (I)



Health Impact Assessment

- **Definition:** evaluation of the effects of an intervention on the health of the population
- Its main goal is to collect evidences on ***potential impacts on health of the interventions***, to select the best intervention for reducing harm or increasing a health benefit (Mindell, 2003)
- Policy makers must design and conduct this kind of studies

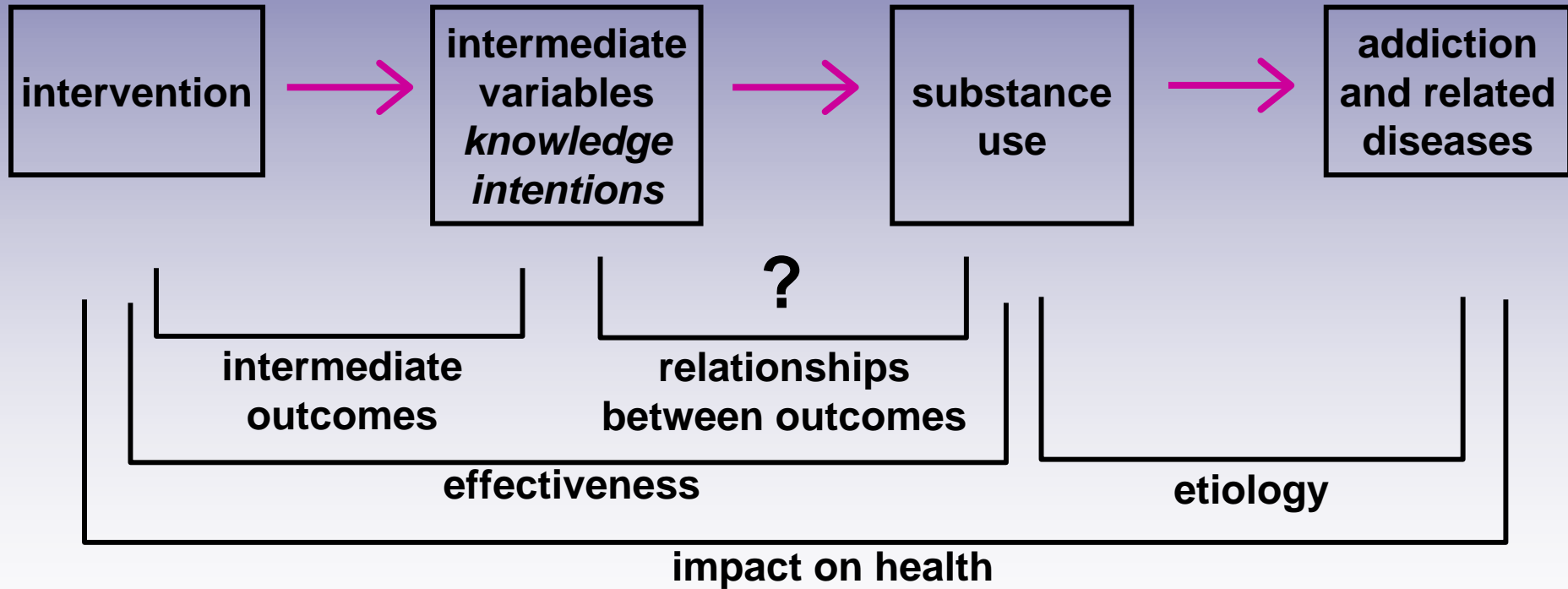
Levels of evaluation in substance use prevention (II)



Evaluation of effectiveness

- **Definition:** evaluation of the extent to which an intervention produces a significant change in the behaviour
- **Appropriate research design:** randomized controlled trials, possibly multicentric, with big sample size
- Research institutes must design and conduct this kind of studies

Levels of evaluation in substance use prevention (III)



Evaluation of intermediate outcomes

- **Definition:** measure of relation between intermediate and final outcomes of an intervention
- **Research design:** *ad hoc* studies
- Research institutes must design and conduct this kind of studies
- **Current state of research:** quite delayed

Responsibility of evaluation

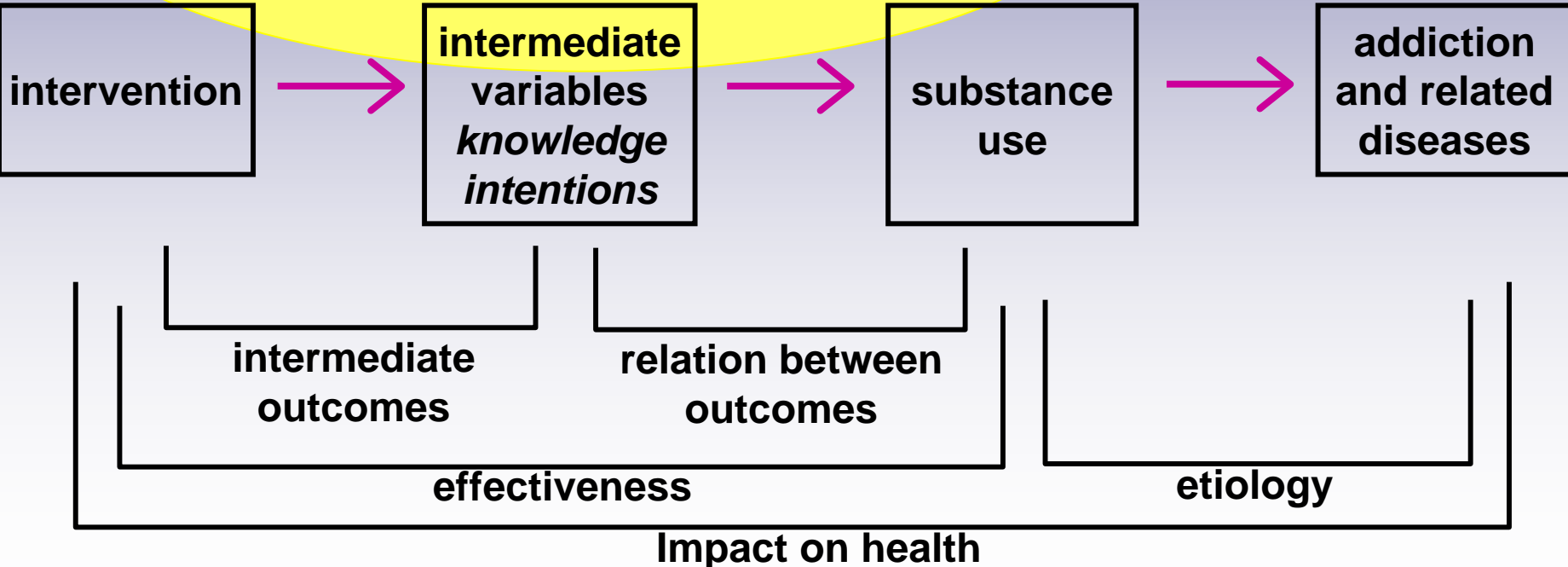
- **Impact evaluation** → policy-makers
- **Effectiveness evaluation** → research
- **Relationships between outcomes:** → research

Responsibility for practitioners

- **ex-ante (a priori) effectiveness evaluation**
 - Evidence-based Prevention: the use of the best evidence on the effectiveness of the interventions for the choice of intervention
- **process evaluation**
 - evaluation on how a program was implemented and operated, compared with the effective (standard) intervention.
 - it may include the evaluation of intermediate outcomes
 - Standardized tools must be used as much as possible (EMCDDA)

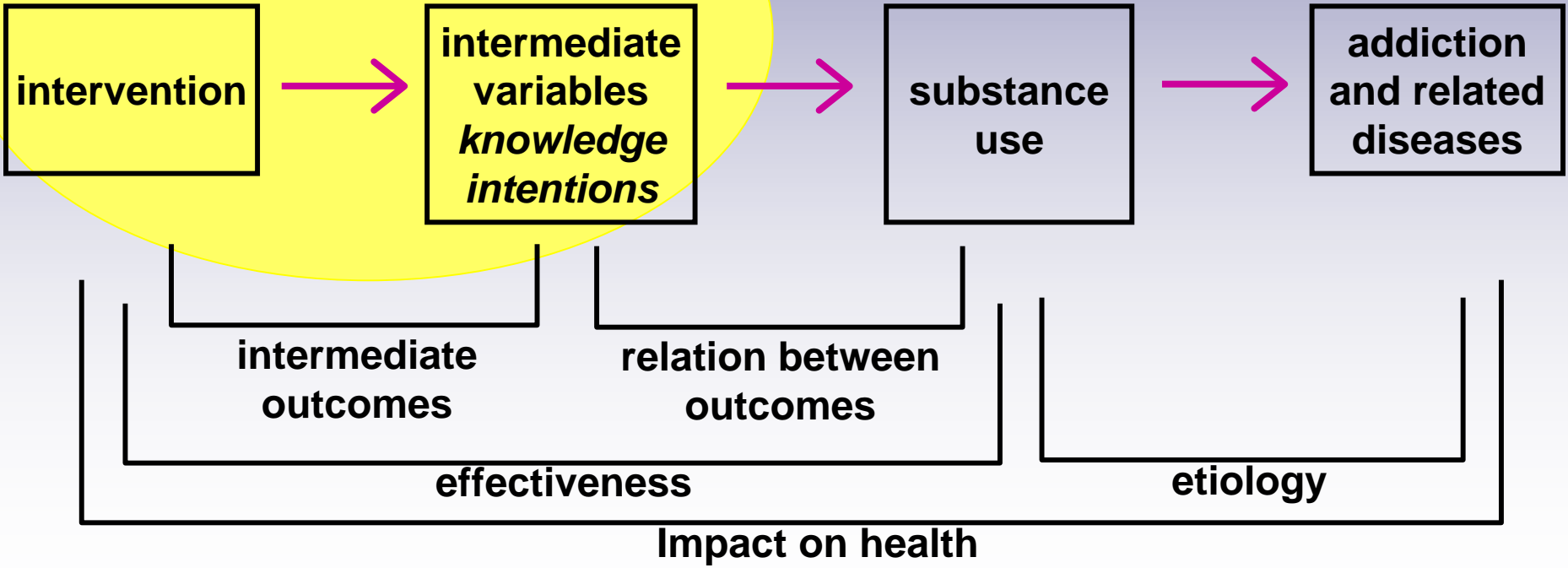
Levels of evaluation in substance use prevention (IV)

ex-ante effectiveness evaluation



Levels of evaluation in substance use prevention (V)

Process evaluation



Systematic reviews

- **Useful tool to make choices**
- **They must be conducted in a rigorous way**
- **Cochrane collaboration is the standard**
- **Population level interventions are poorly studied**



**systematic reviews on public health interventions
are needed**



***School-based prevention for illicit
drugs' use:
a systematic review***

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**

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 young persons can be reached
 - schools can adopt and enforce a broad spectrum of educational policies

Background: (II)

- **There is a huge variability in schools-based programmes**
- **Some evaluations demonstrated a higher drug consumption among intervention harm (Dukes 1997; Hawthorne 1996)**
- **A systematic review has been considered a priority by the Cochrane Drug and Alcohol Review Group (CDAG)**

Background: (II)

- **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-user**
 - **We are responsible for adolescents who start using drugs because of the intervention**
 - Adolescent are involved
 - The target population **did not ask for an intervention**

Methods: Literature search

- **The search strategy was elaborated according to the Cochrane Collaboration method**
- **The following sources were searched**
 - Medline (1966 - February 2004)
 - Embase (1988 - February 2004)
 - ERIC (1988 - February 2004)
 - Sociological Abstracts (1963-2000)
 - Psychinfo (1967 - February 2004)
 - Cochrane Central Register of Controlled Trials (1st update 2004)
 - ACP Journal Club (1991 - February 2004)
 - Cochrane Database of Systematic Reviews (1st update 2004)
 - Database of Abstracts of Reviews of Effects (1st update 2004)
 - Cochrane Drug and Alcohol Review Group Register (1st update 2004)
- **Specific search strategies were used for each database**
- **No language restrictions were adopted**

Methods: Inclusion criteria

All RCTs and Controlled Prospective Studies (CPSs)
evaluating any intervention program

versus a control condition

- usual curricular activities
- another school-based drug prevention program

and designed to prevent substance use

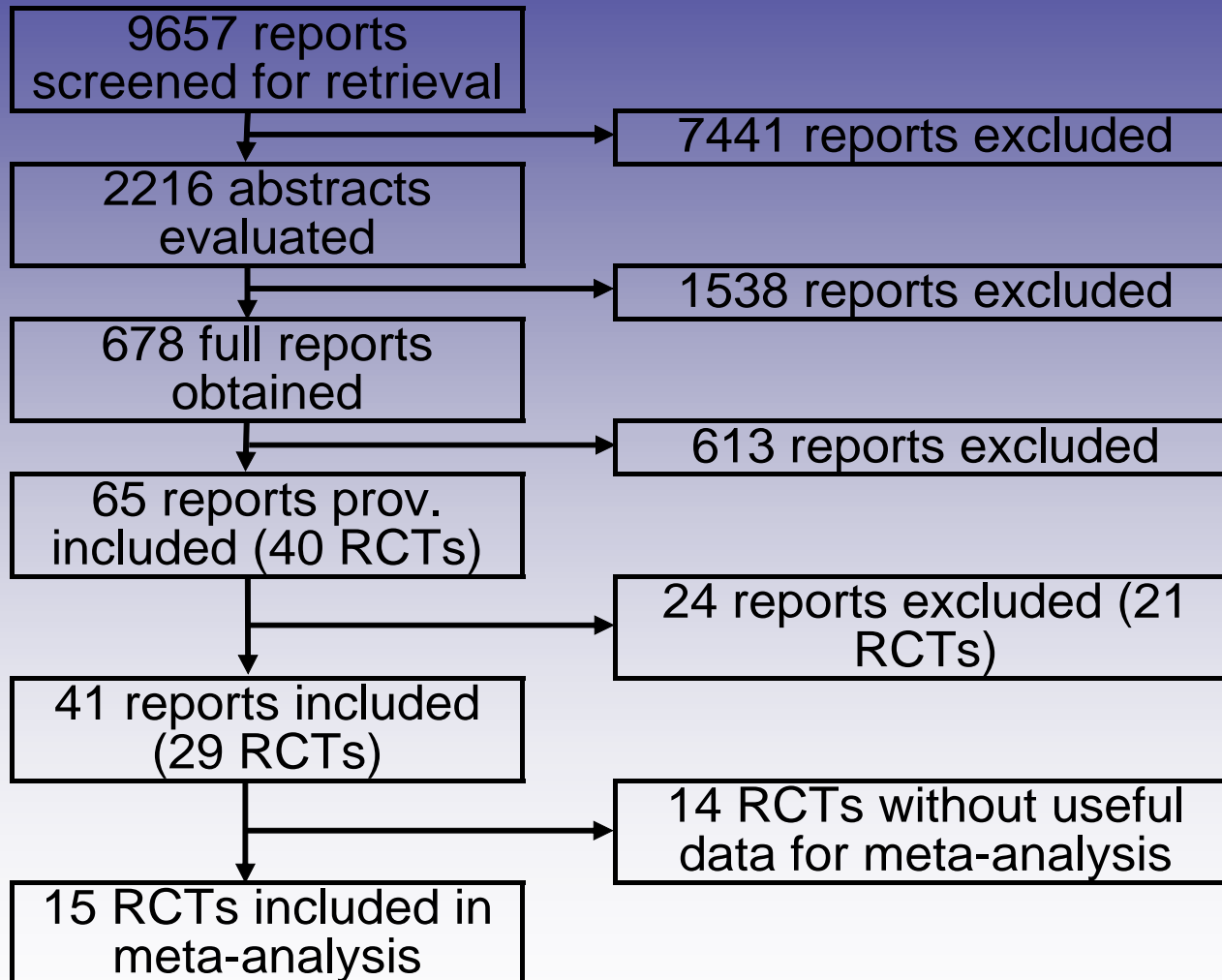
in a school setting

were considered

Methods: Data collection and evaluation

- Review articles, and all the included studies were scanned to identify other significant studies
- Research teams, and 18 authors of the included and excluded studies were contacted to discover unpublished researches/results
- The search strategy identified 9657 reports
 - 7441 reports were excluded based on titles
 - 2216 abstracts were evaluated by two reviewers
 - 1538 reports were excluded based on abstracts
 - 678 full reports were obtained
 - 613 reports were excluded (374 for methodological reasons, 128 were reviews, 76 were community programs, 35 were alcohol focused programs)

Flow chart of the review



Methods: Data extraction

- **678 studies** were independently assessed by two reviewers
- **65 reports** met the inclusion criteria (40 RCTs)
 - 24 (21 RCTs) of them were excluded for methodological reasons
- **41 reports** were included (29 RCTs)
 - Data were independently extracted by two reviewers using a standardized checklist
- Disagreements were settled by a third reviewer
- 14 authors were contacted in order to provide supplementary analysis data
- Only **15 RCTs** provided data useful for meta-analysis

Methods: 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**

Methods: program classification

The interventions were also classified according to

- type of teaching:
 - **interactive programs:** participants were actively involved in the activities
 - **passive programs**
- people involved in program administration:
 - **teachers**
 - **external educators**
 - **peers**

Methods: Outcomes

- **The following outcomes were considered**
 - **Final outcomes**
 - use of drugs
 - **Intermediate outcomes**
 - drug knowledge
 - drug attitudes
 - acquirement of personal skills
 - peers/adults drug use
 - intention to use drugs

Methods: Quality assessment

- The quality of the studies included was assessed by two reviewers
- according to the CDAG's check list studies were grouped in 3 classes:
 - A: low risk of bias (scores 9-11)
 - B: moderate risk of bias (scores 6-8)
 - C: high risk of bias (scores 0-5)
- Disagreements were settled by a third reviewer

Methods: Statistical analysis

- Data were analysed with **RevMan software**
- A **standardized effect size** was calculated for each study, in function of its outcome
- Wherever possible, **summary relative risks and 95% confidence intervals** were calculated with a random effects model; for continuous outcomes measured in different ways a standardized mean difference (SMD) between groups was calculated
- When two or more studies were included in the meta-analysis, a test of **heterogeneity** was applied
- The effect of the low quality studies on the overall results was determined by a **sensitivity analysis**, with inclusion or exclusion the class C studies (no differences emerged)

Included studies

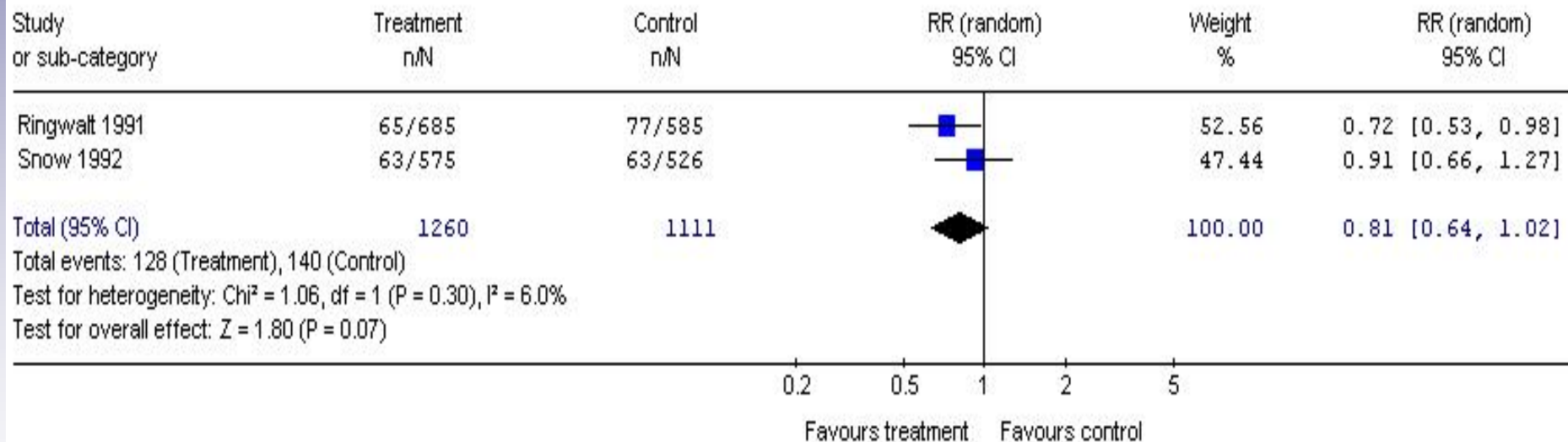
- **29 studies (41 reports)** were included
- 14 did not present data useful for the inclusion in the meta-analyses
- 18 studies were of **6 and 7th grade** students
- in 18 studies the evaluation was based on **post-test** assessment; 13 provided data at 1 year follow-up
- **all but one** were conducted in the **USA**. Only 1 RCT was conducted in the UK
- Most studies evaluated **skills focused programs** (n=25); **affective programs** were assessed by 6 studies, and 6 included a **knowledge focused arm**
- **interactive techniques** were used in 27 studies.
- Administrators were **external educators** in 20 studies, **teachers** in 10, **peer leaders** in 4, and **others** (policemen) in 2

Results

Skills versus usual curricula

drugs use

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

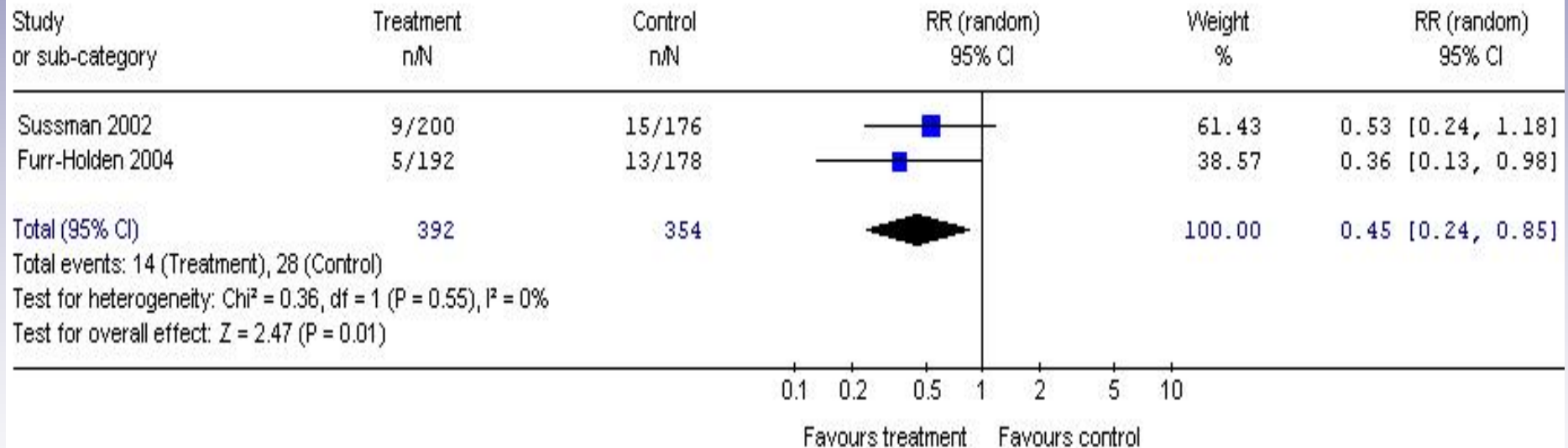


Results

Skills versus usual curricula

hard drugs use

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

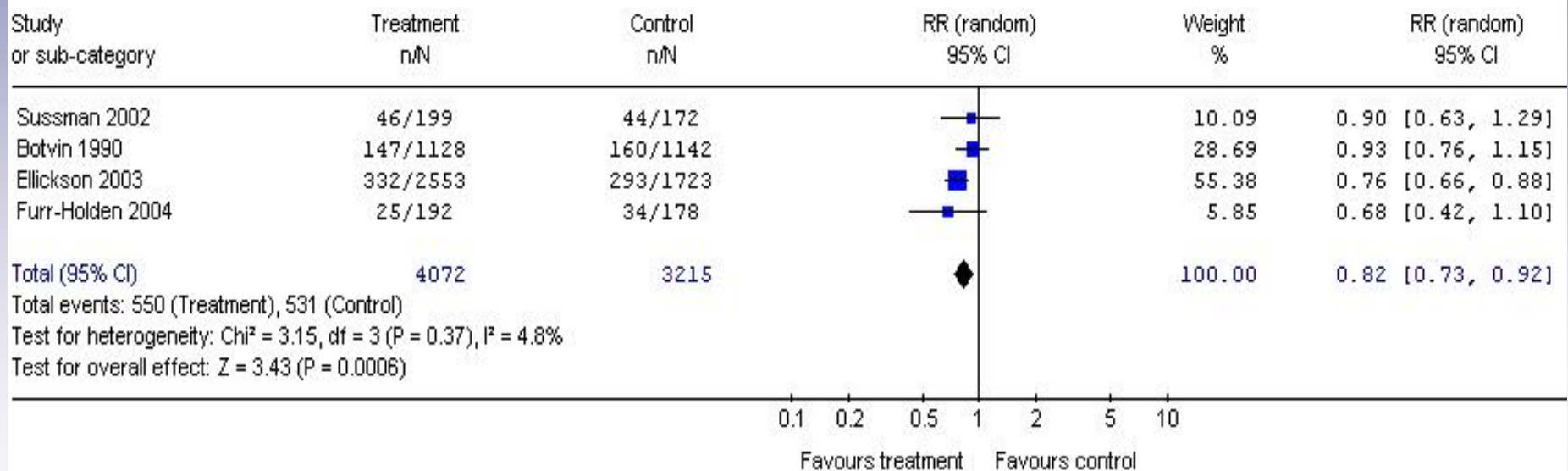


Results

Skills versus usual curricula

marijuana use

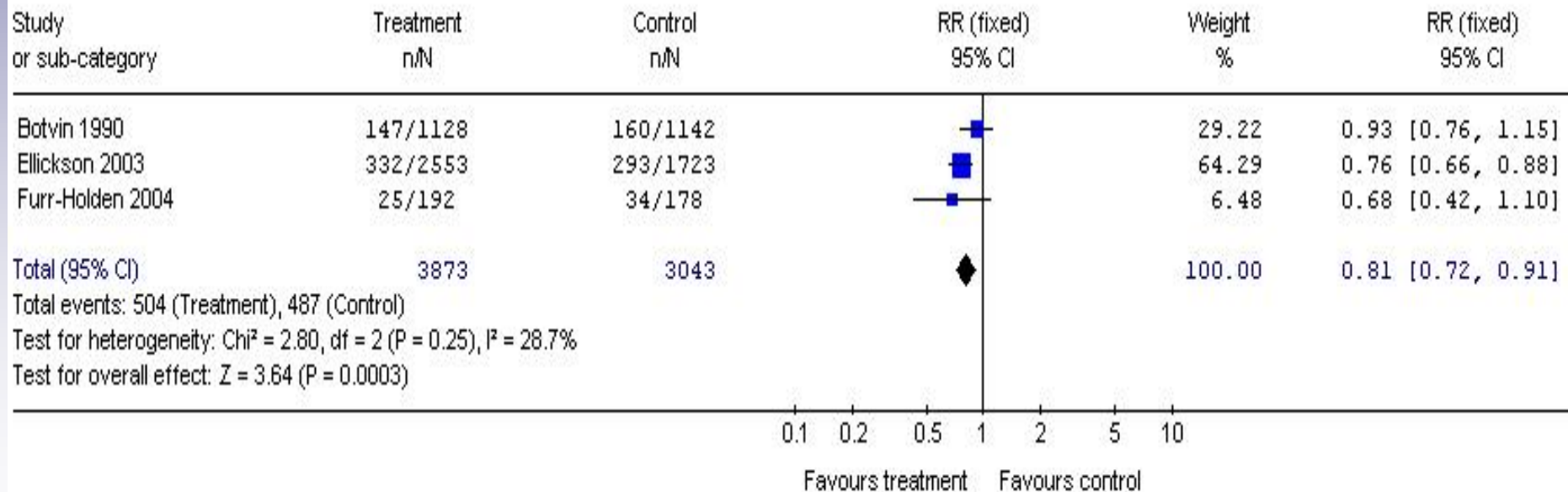
Review: School-based prevention for illicit drugs' use.
 Comparison: 02 skills vs usual curricula
 Outcome: 08 marijuana use (all studies)



Results

Skills versus usual curricula marijuana use (without C class study)

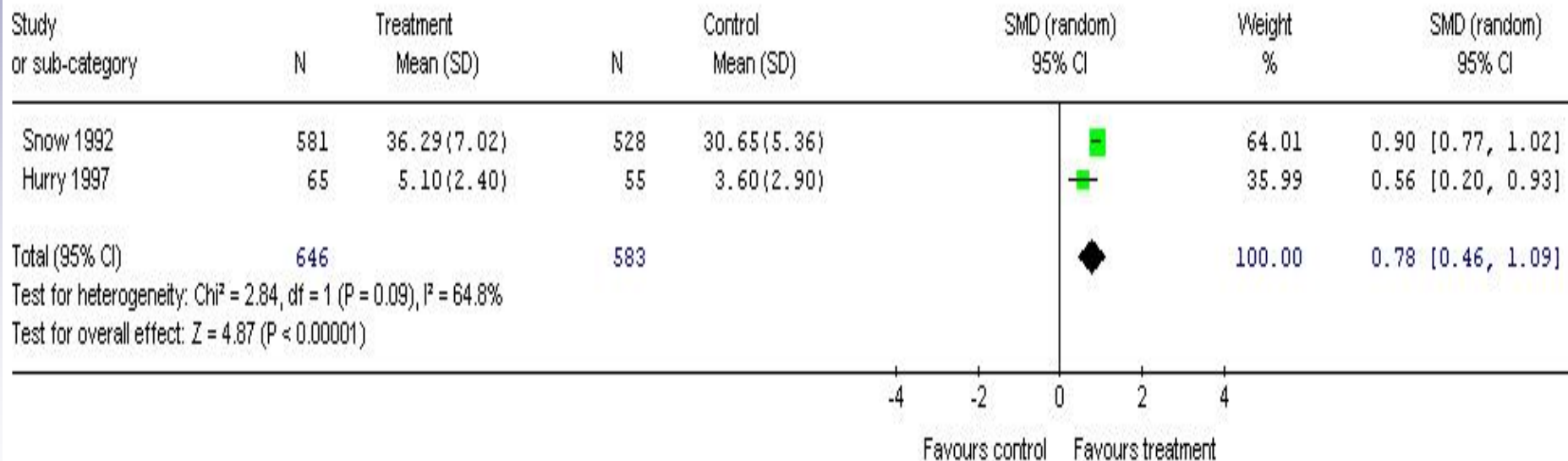
Review: School-based prevention for illicit drugs' use.
 Comparison: 02 skills vs usual curricula
 Outcome: 09 marijuana use (only A-B quality class studies)



Results

Skills versus usual curricula decision making skills

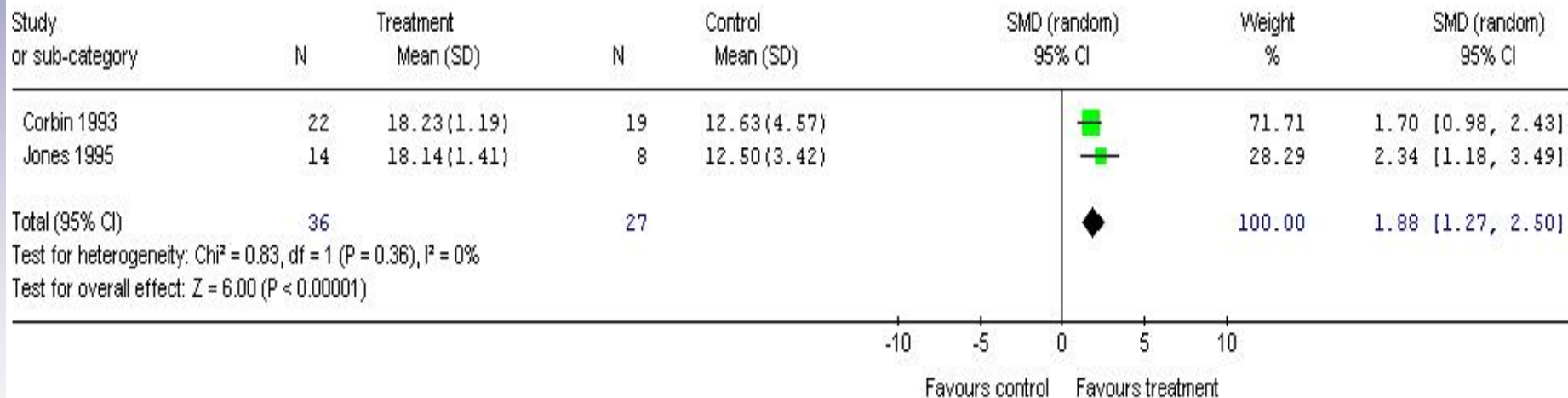
Review: School-based prevention for illicit drugs' use.
 Comparison: O2 skills vs usual curricula
 Outcome: O2 decision making skills



Results

Affective versus usual curricula drug knowledge

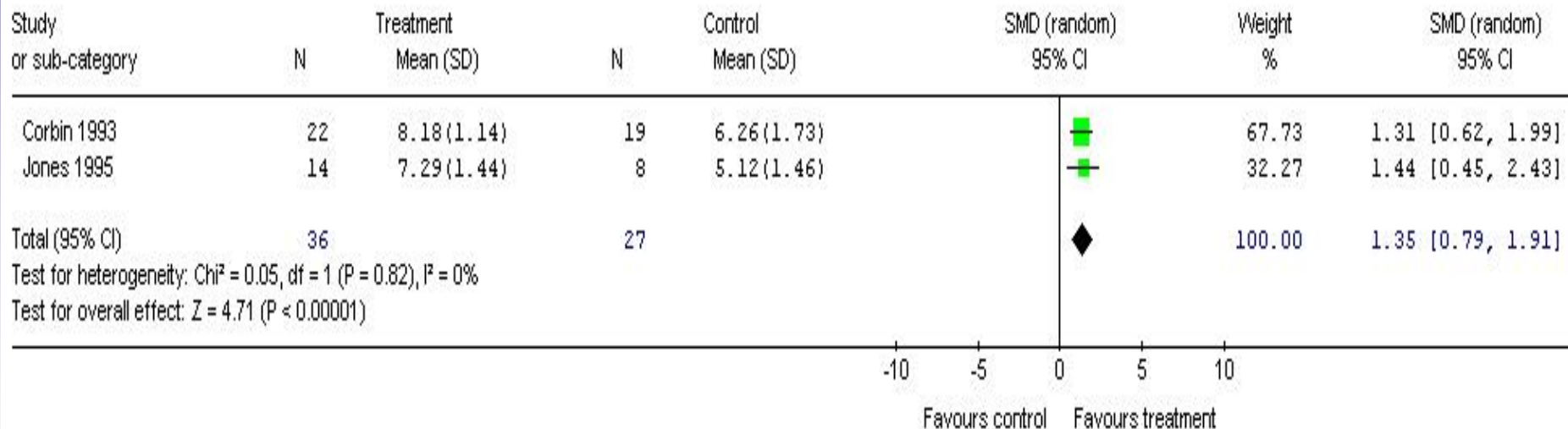
Review: School-based prevention for illicit drugs' use.
 Comparison: 05 affective vs usual curricula
 Outcome: 01 drug knowledge



Results

Affective versus usual curricula decision making skills

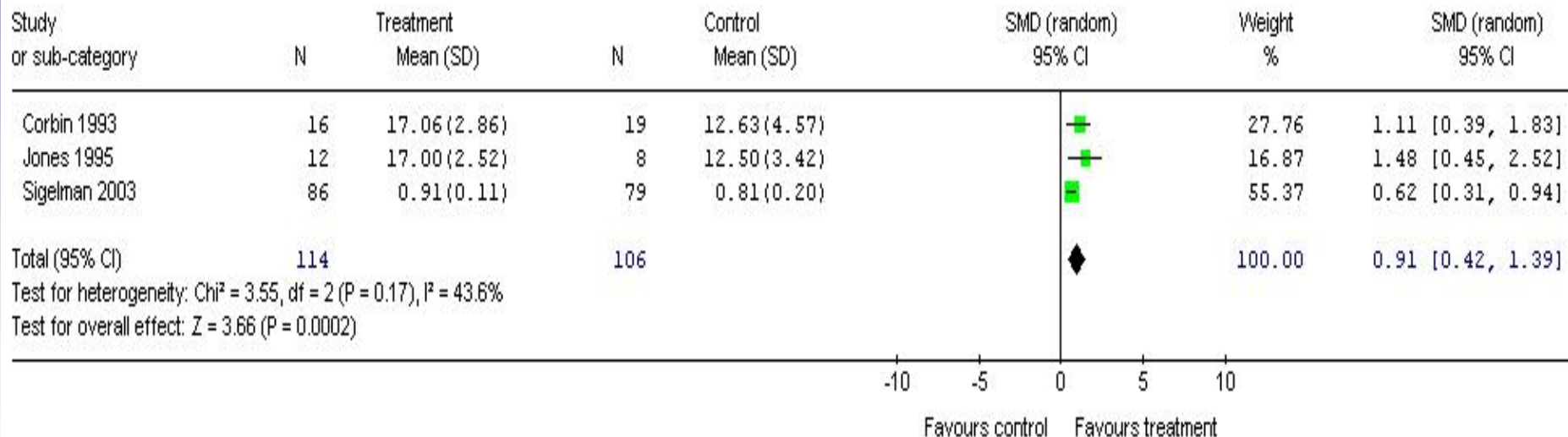
Review: School-based prevention for illicit drugs' use.
 Comparison: 05 affective vs usual curricula
 Outcome: 02 decision making skills



Results

Knowledge versus usual curricula drug knowledge

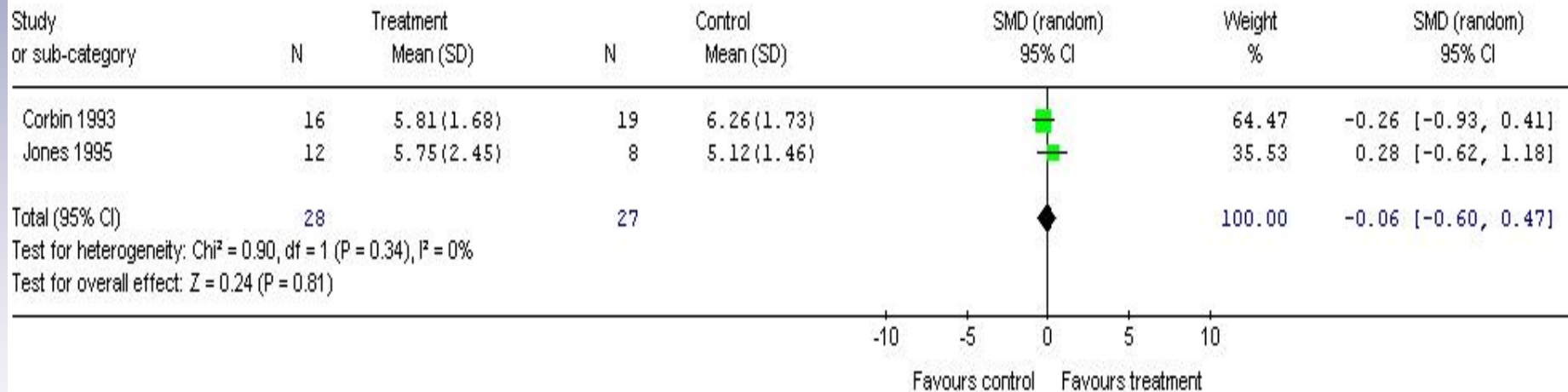
Review: School-based prevention for illicit drugs' use.
Comparison: 01 knowledge vs usual curricula
Outcome: 01 drug knowledge



Results

Knowledge versus usual curricula decision making skills

Review: School-based prevention for illicit drugs' use.
Comparison: 01 knowledge vs usual curricula
Outcome: 02 decision making skills



the result is the same for assertiveness

Summary of meta-analytic results

- Skills-based programs **reduce**
 - **drug use** (RR=0.81; CI95%: 0.64, 1.02)
 - **hard drug use** (RR=0.45; CI95%: 0.24, 0.85)
 - **marijuana use** (RR=0.82 CI95%: 0.73, 0.92)
- Skills-based programs **improve**
 - **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)

Results

Interactive vs passive techniques

- Only three studies provided data suitable for meta-analysis: results were **not statistically significant** for drug knowledge, decision making skills, self-esteem, self-efficacy, and marijuana use
- However, interactive techniques were more effective in reducing **hard drug use** in the study by Sussman (RR=0.43; CI95%: 0.19-0.99)

Results

The role of peers

- When administered by **peers as opposed to teachers**, programs were significantly more effective with regard to marijuana use, knowledge and attitudes towards this drug at post test
- Marijuana attitudes at 1 year follow-up become lower in the **teacher-led group**
- When compared with **external educators**, the effect of **peers** was evident for drug knowledge (WMD=-3.42; CI95%: -6.81, -0.03), but not significant for the other outcomes

Conclusions: (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
- This results persist even years after the intervention, with most of the RCTs included having a satisfactory methodological quality (mainly quality score=B)

Conclusions: (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

Conclusions: (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 this, **1 would be prevented** by the intervention, which corresponds to the **20% of the new initiators**

Limitations

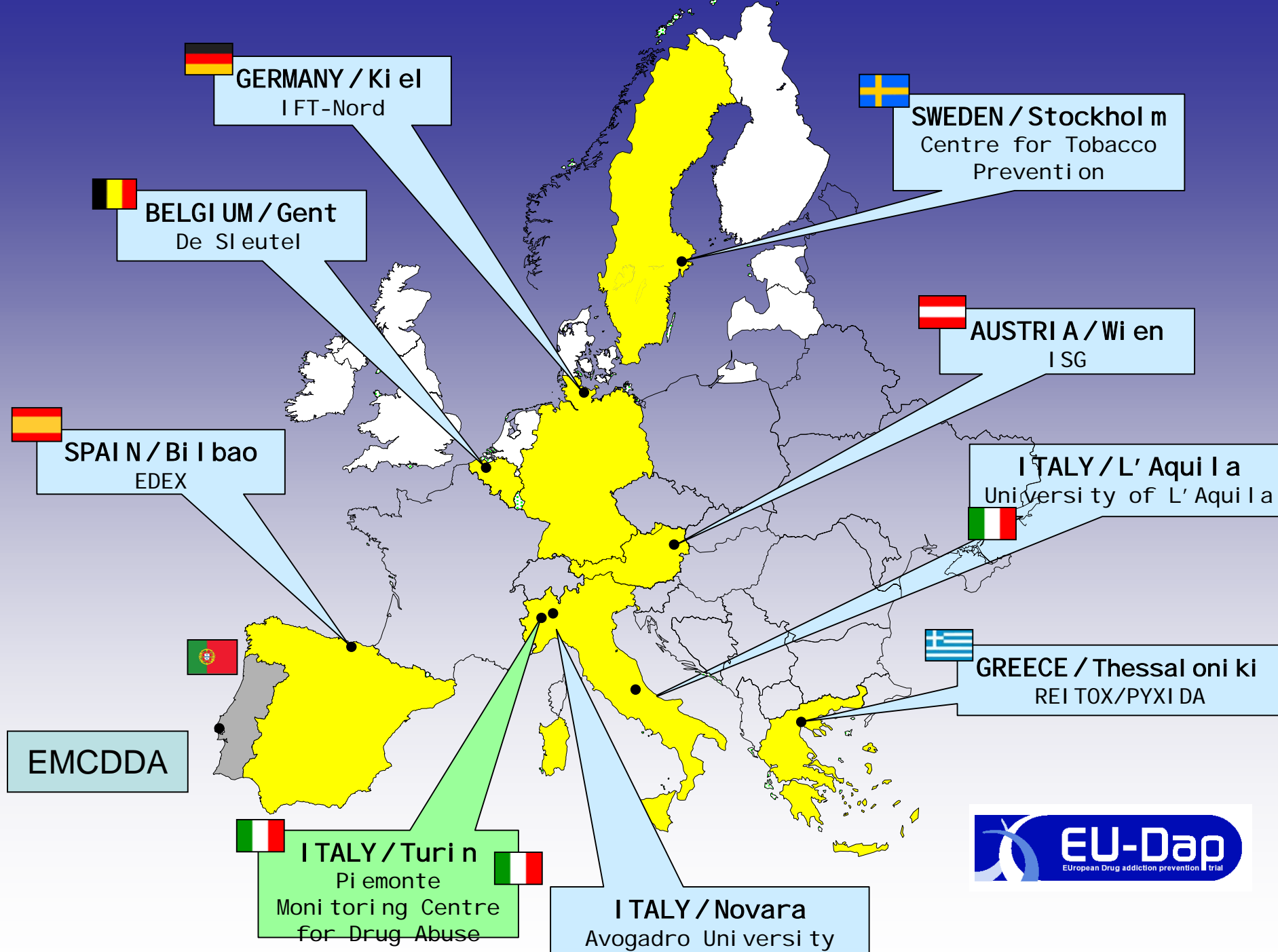
- none of the RCTs satisfied all the quality criteria of the review
- most results were outcomes at post test and few data were from long-term follow-ups
- many studies did not present effect measures but only statistical indicators (f, p...) so it was impossible to combine them in the meta-analysis
- measure of effects were very heterogeneous
- the control for heterogeneity was not always satisfactory
- only six studies were designed to take account of the cluster effect
- all but one of the 29 RCTs included were conducted in the USA



Studio EU-Dap

**European Drug Addiction
Prevention trial**

- **Cluster randomized controlled trial**
- **Funded by the European Community**
- **involved 7 European Countries**
- **Main aims:**
 - **To build a school-based european prevention program (“*Unplugged*”)**
 - **To evaluate the efficacy of the program in reducing the use of drugs**



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

EMCDDA

ITALY / Turin
Piemonte
Monitoring Centre
for Drug Abuse

ITALY / Novara
Avogadro University

GREECE / Thessaloniki
REI TOX/PYXI DA



- 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, who participated to a 3 days specific workshop
- 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



AUTO-GENERAZIONE DEL
CODICE ANONIMO



Individual code



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



Questionnaire



- 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%

Enrollment

Schools assessed
n=344

Schools excluded
n=174

Schools randomised
n=170

Allocation

Basic arm
Schools:
- allocated=35
- refused=9
- included=26
Students:
- enrolled=1190

Parents arm
Schools:
- allocated=35
- refused=8
- included=27
Students:
- enrolled=1164

Peers arm
Schools:
- allocated=32
- refused=7
- included=25
Students:
- enrolled=1193

Control arm
Schools:
- allocated=68
- refused=3
- included=65
Students:
- enrolled=3532

Follow up

Schools:
- drop out = 0
Students:
- drop out = 0
- unmatched=106

Schools:
- drop out = 0
Students:
- drop out = 0
- unmatched=96

Schools:
- drop out = 1
Students:
- drop out = 46
- unmatched=103

Schools:
- drop out = 1
Students:
- drop out = 73
- unmatched=285

Analysis

Schools:
- analyzed=26
Students:
- analyzed=1084

Schools:
- analyzed=27
Students:
- analyzed=1068

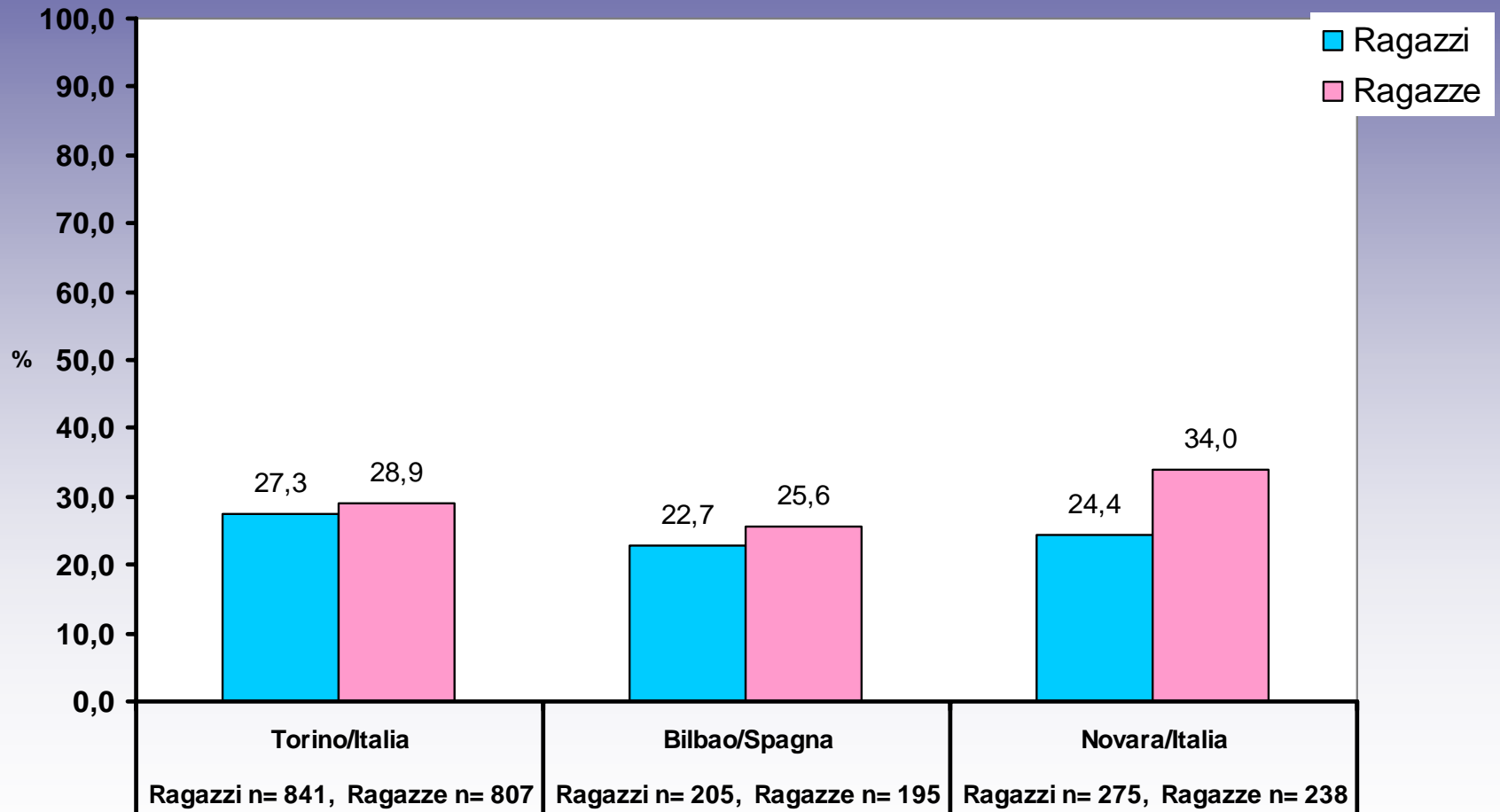
Schools:
- analyzed=24
Students:
- analyzed=1044

Schools:
- analyzed=64
Students:
- analyzed=3174

	Study Arm					
	Controls		All 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

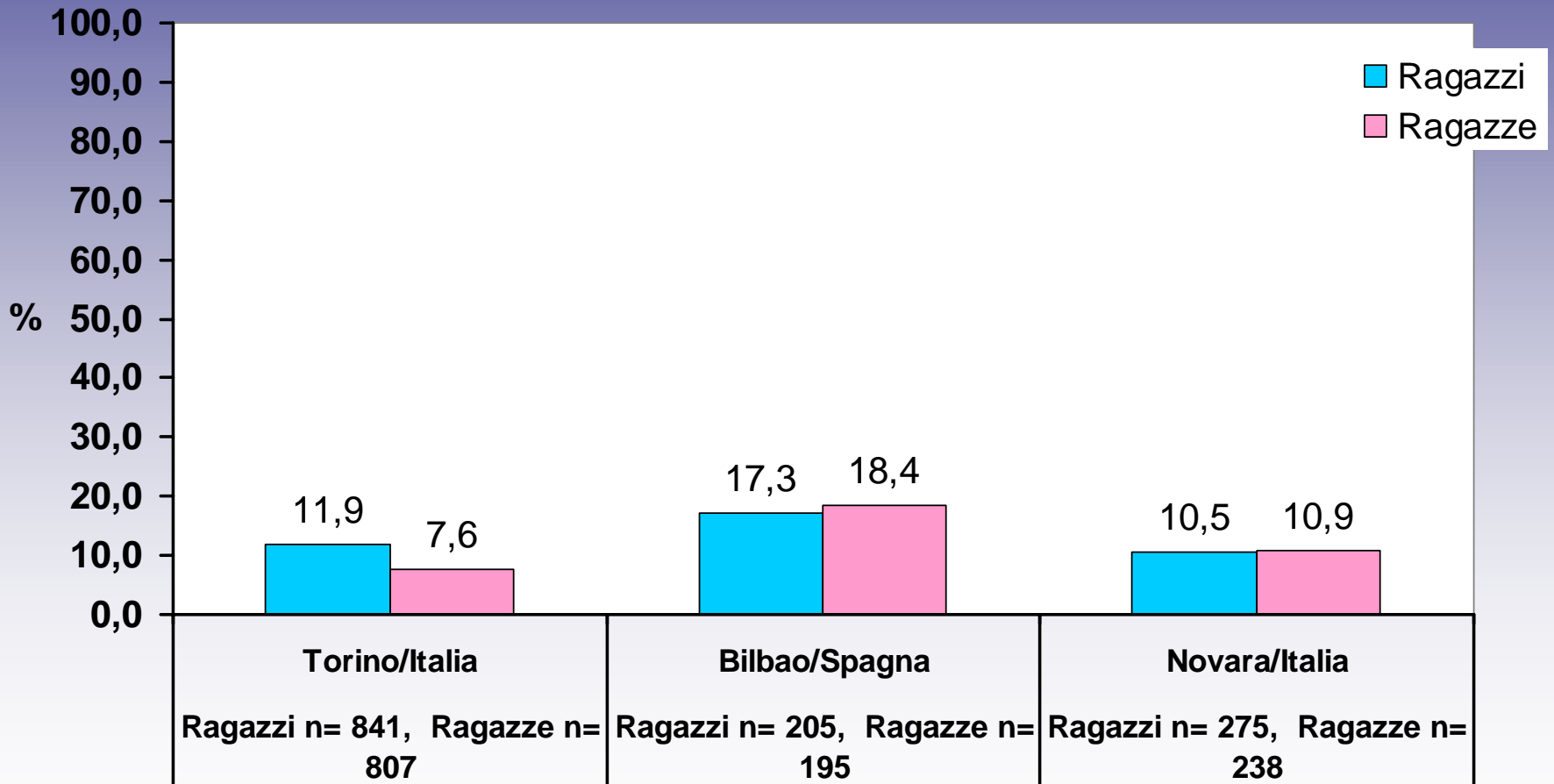
Smoking cigarettes

I smoked at least one cigarette in the last 30 days



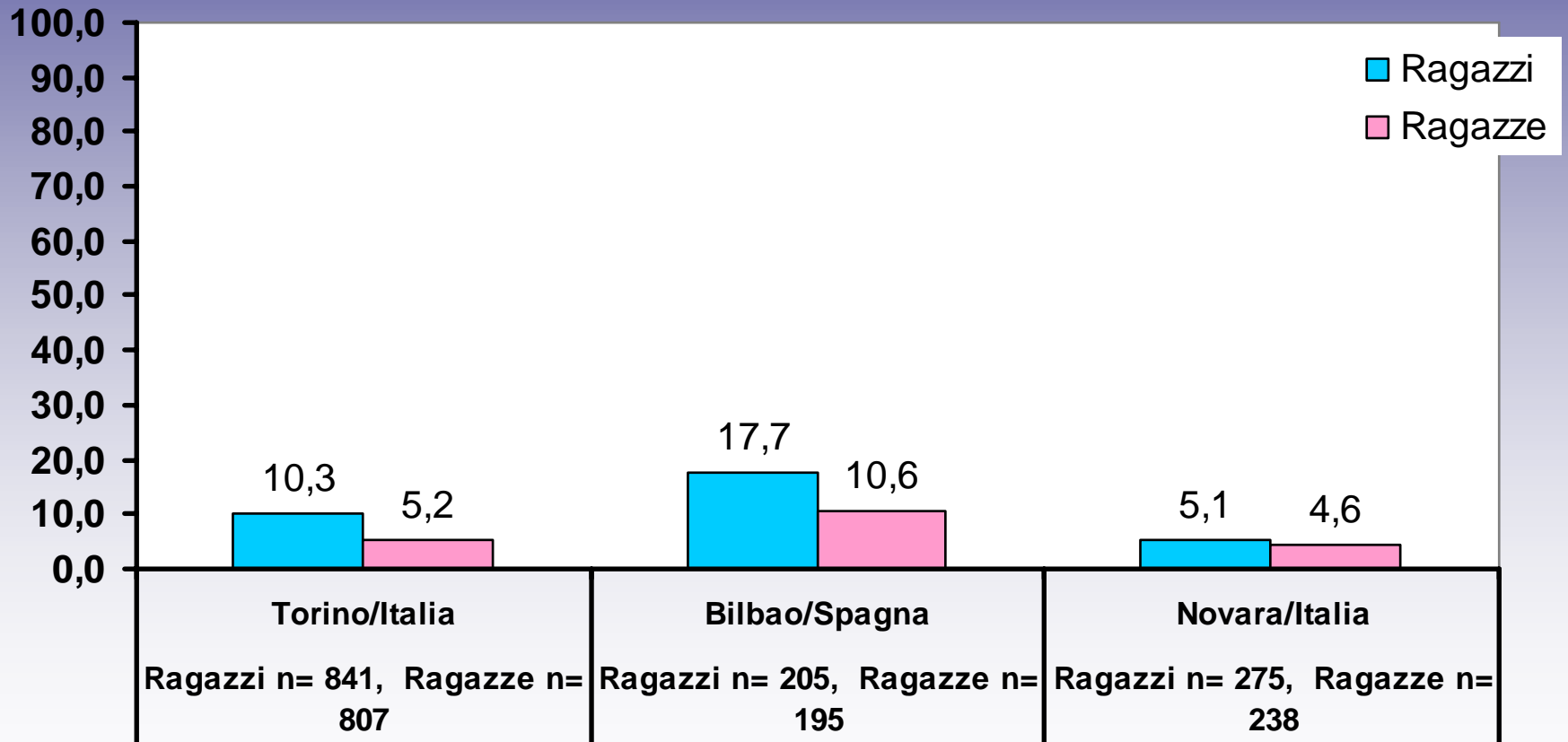
Have been drunk

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



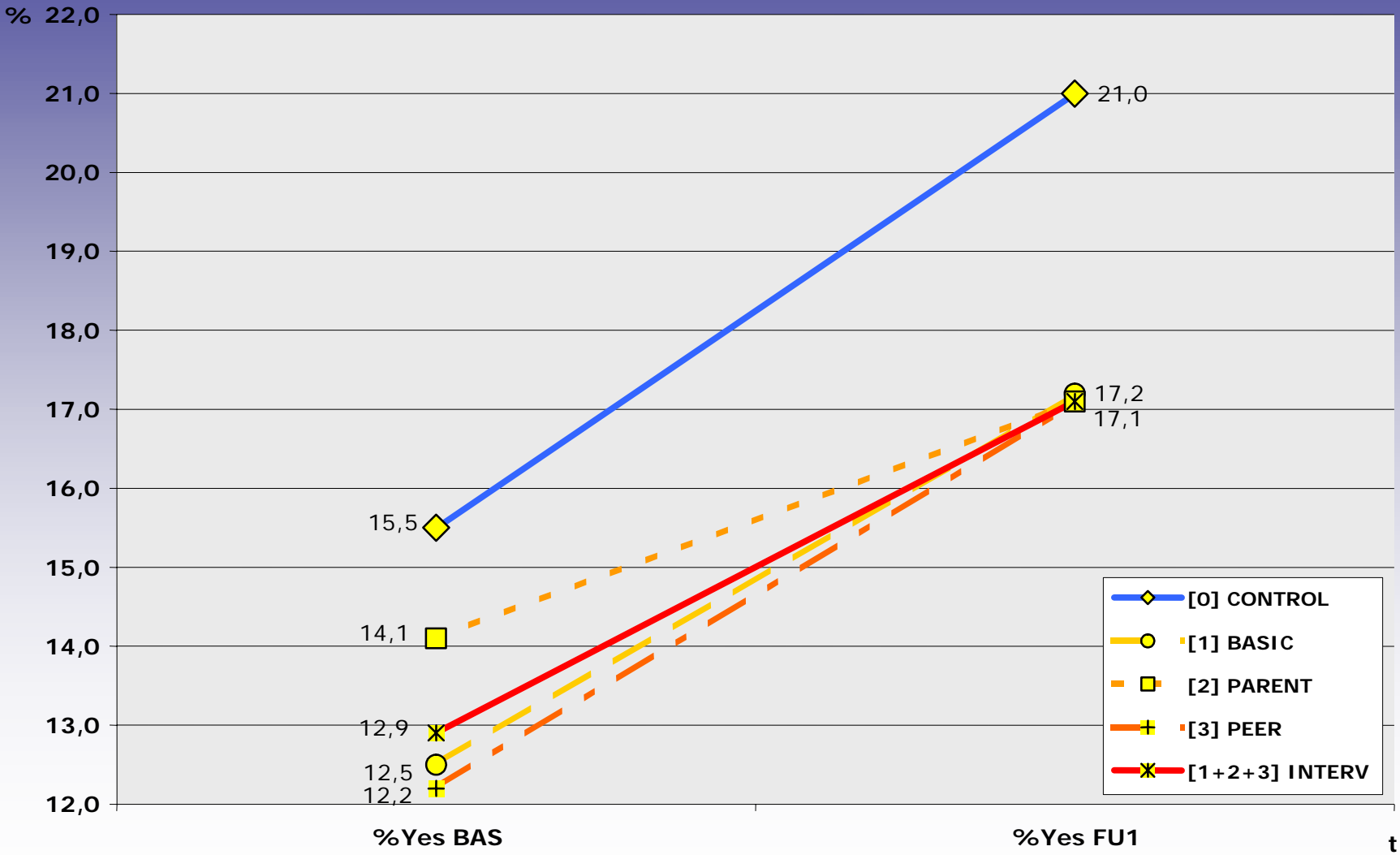
Smoking cannabis

I smoked cannabis at least ONCE in the last 30 days

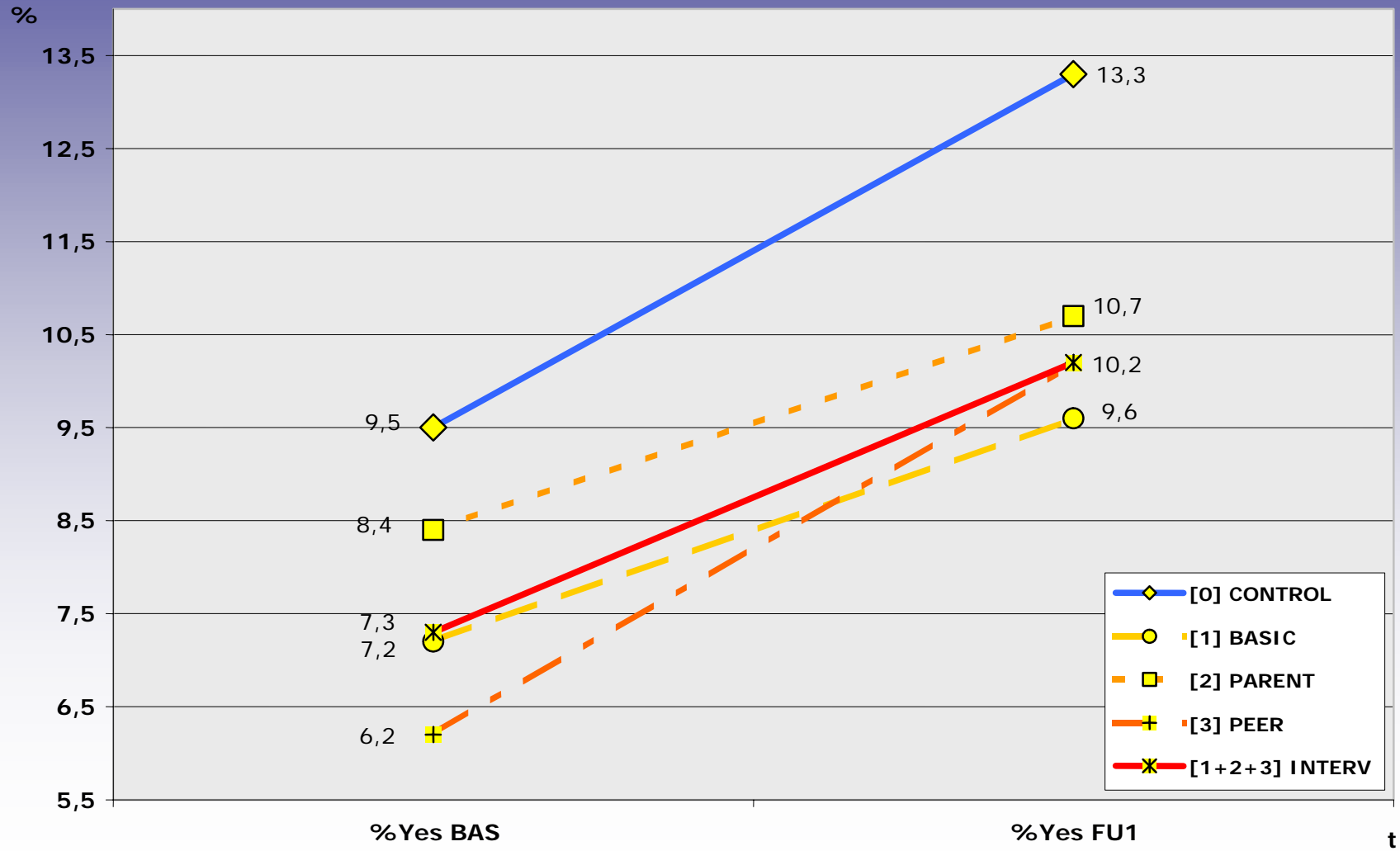


- ***ALO smoking***: At least once in the last 30 days
- ***Regular Smoking***: At least 6 times in the last 30 days
- ***Daily smoking***: At least 20 times in the last 30 days
- ***ALO drunkenness***: At least once in the last 30 days
- ***Regular drunkenness***: At least 3 times in the last 30 days
- ***ALO cannabis***: At least once in the last 30 days
- ***Regular cannabis***: At least 3 times in the last 30 days
- ***ALO drugs***: At least once in the last 30 days (all drugs except cigarettes and alcohol)

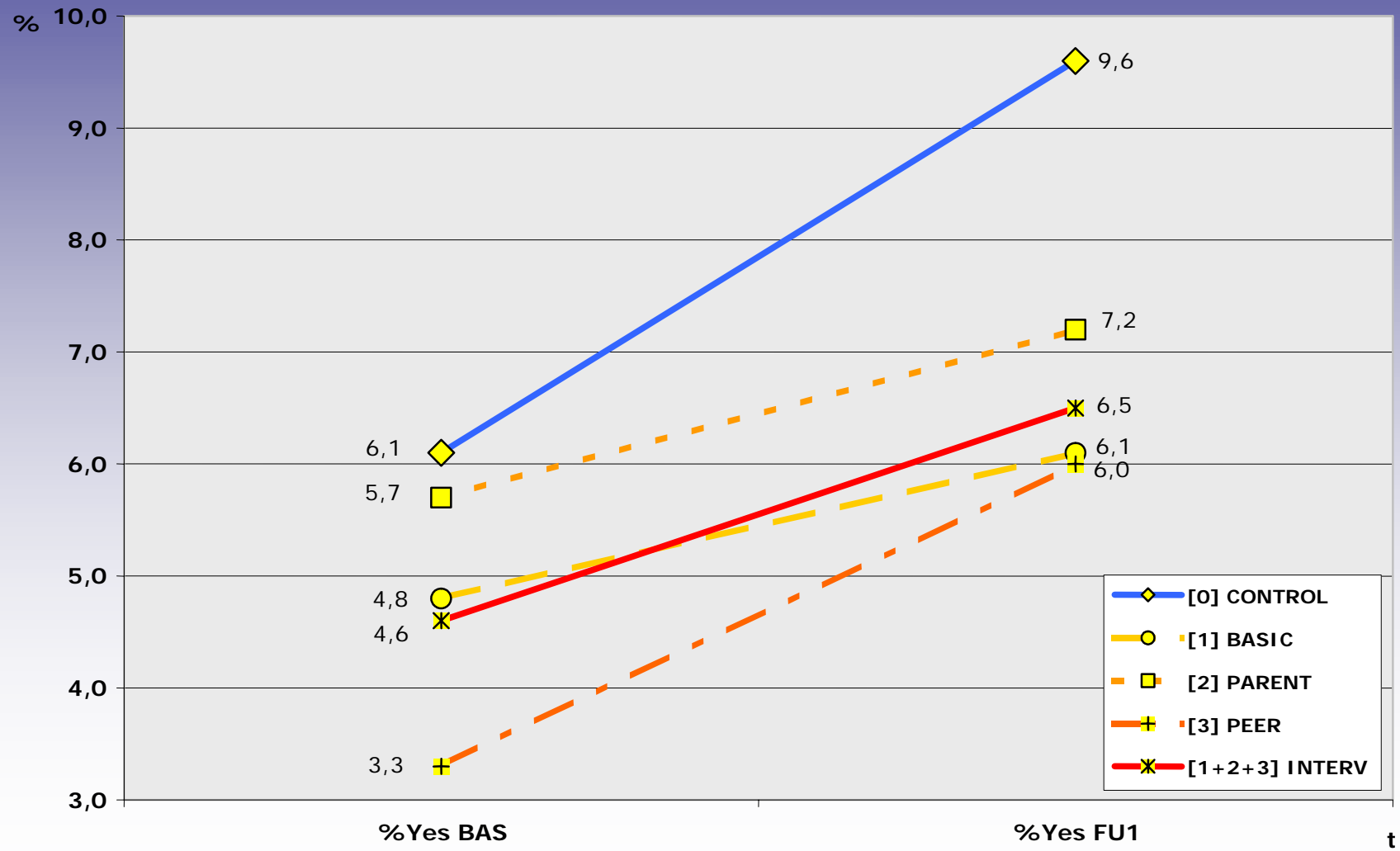
ALO smoking



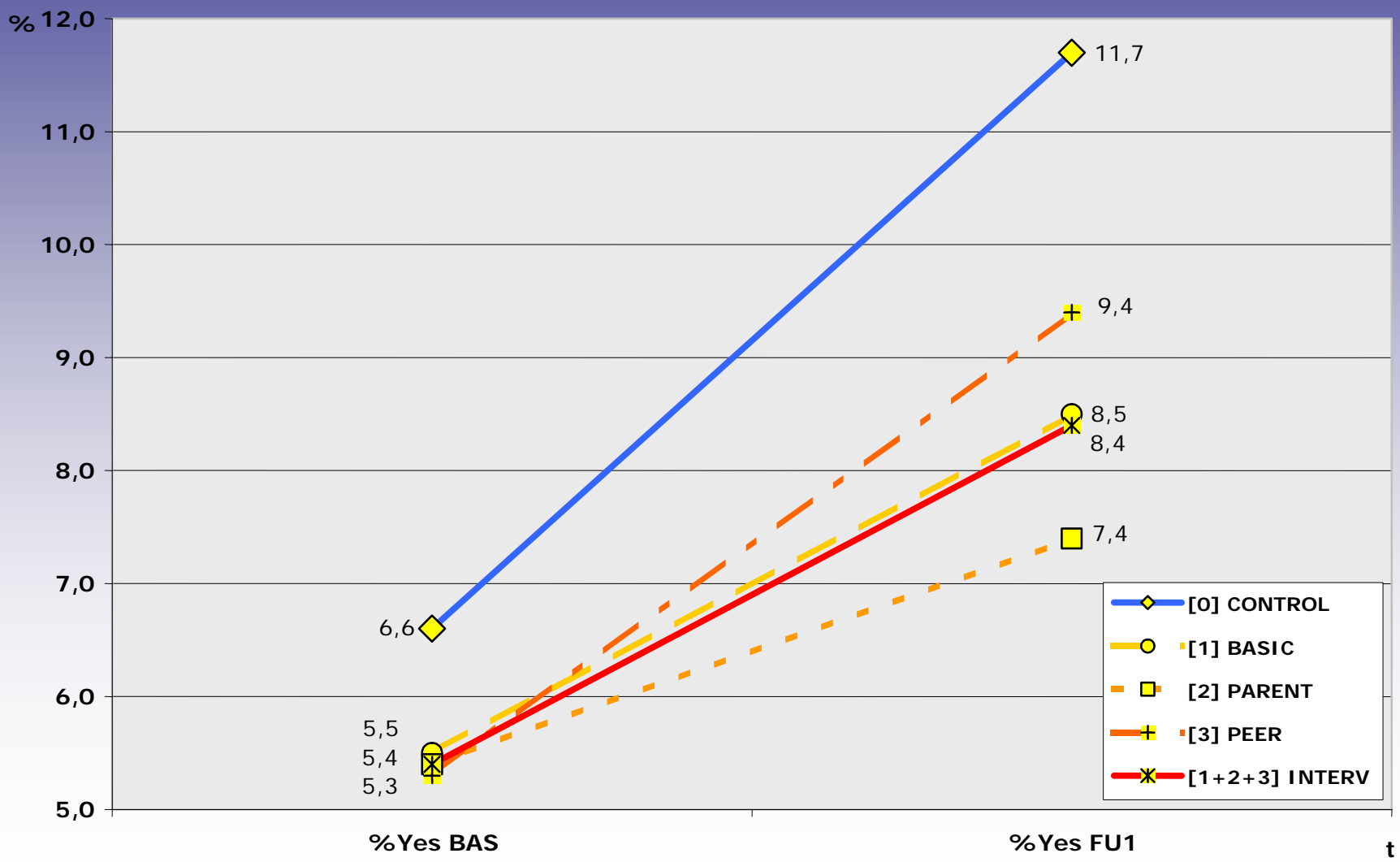
Regular smoking



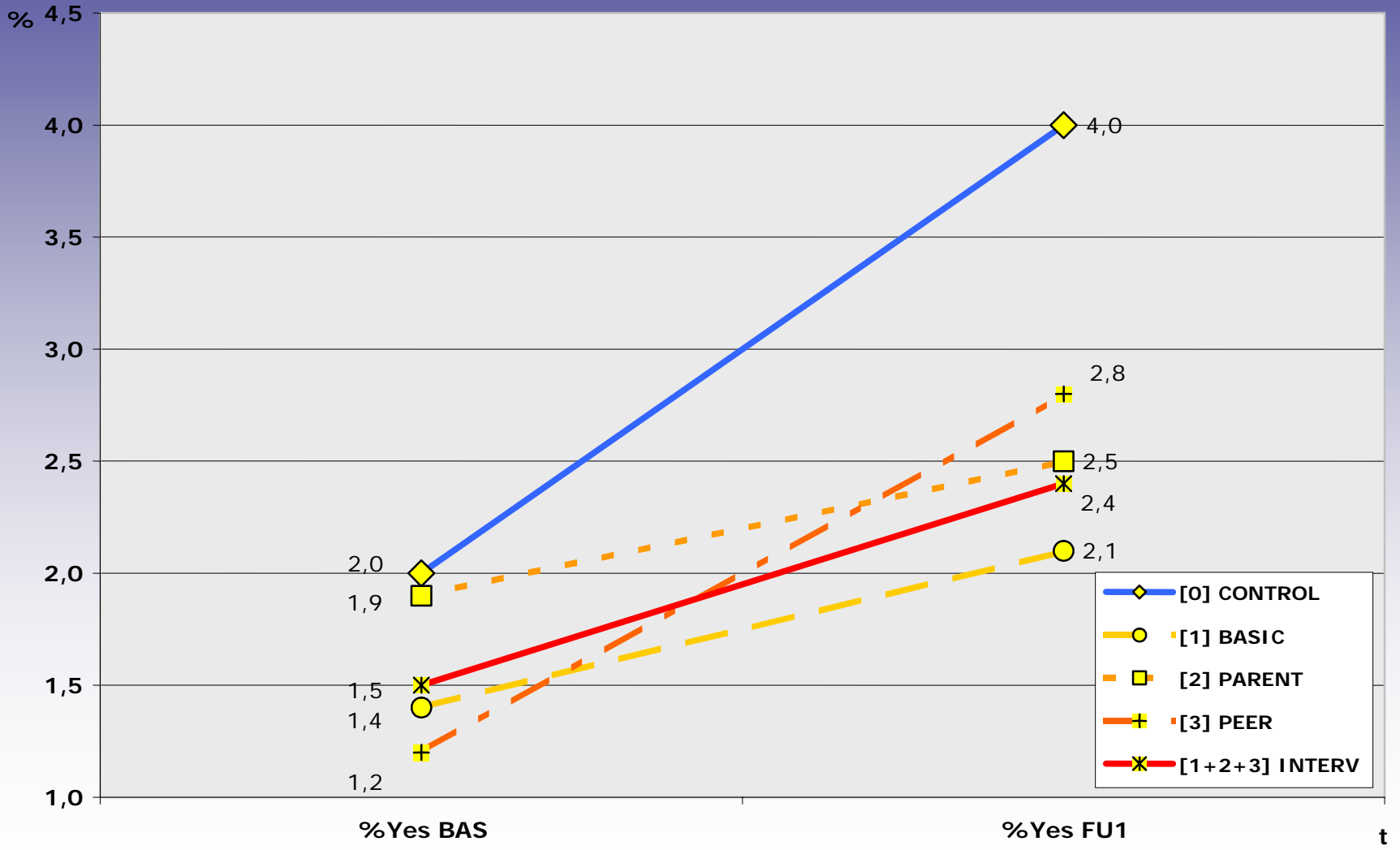
Daily smoking

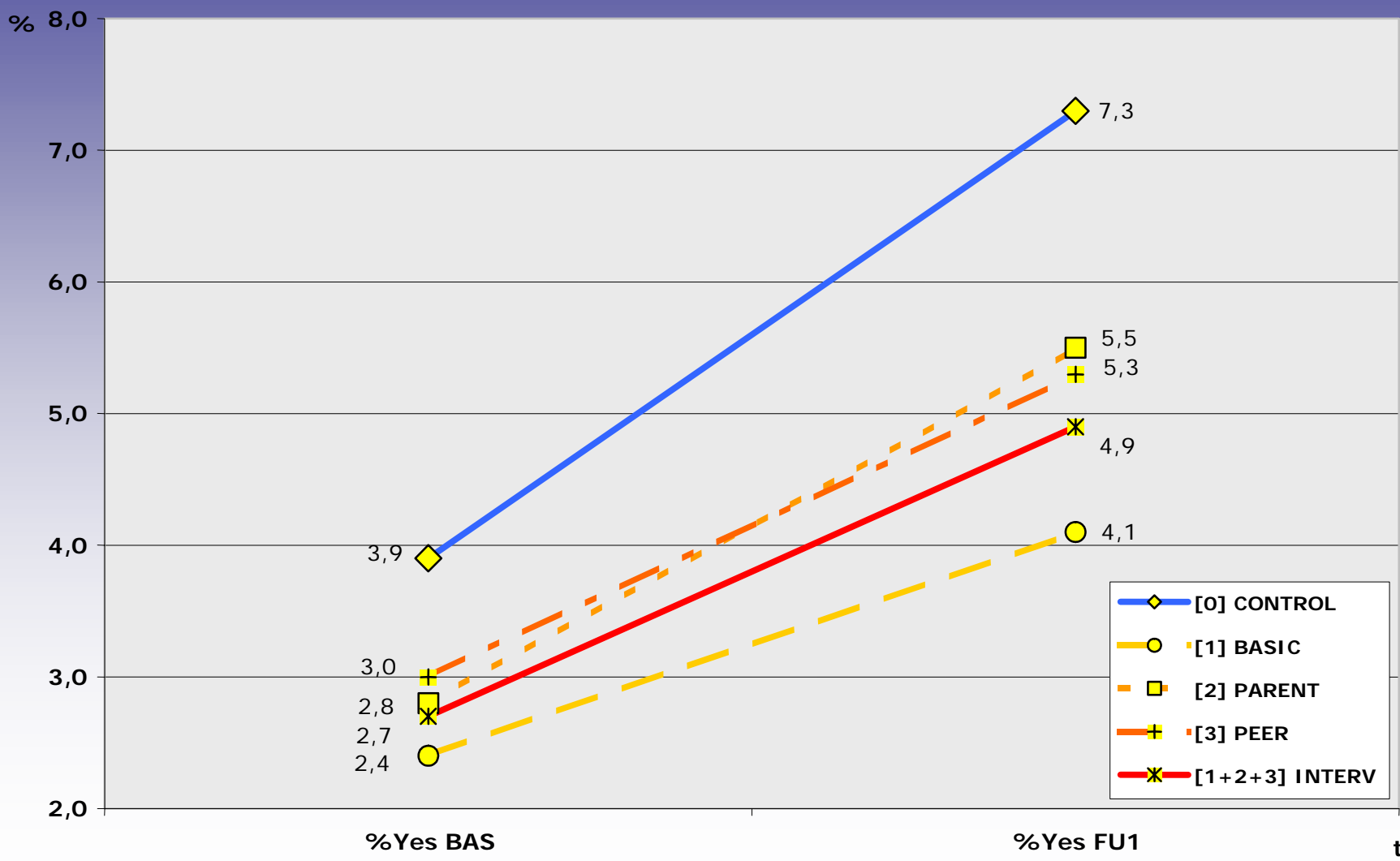


ALO drunkenness

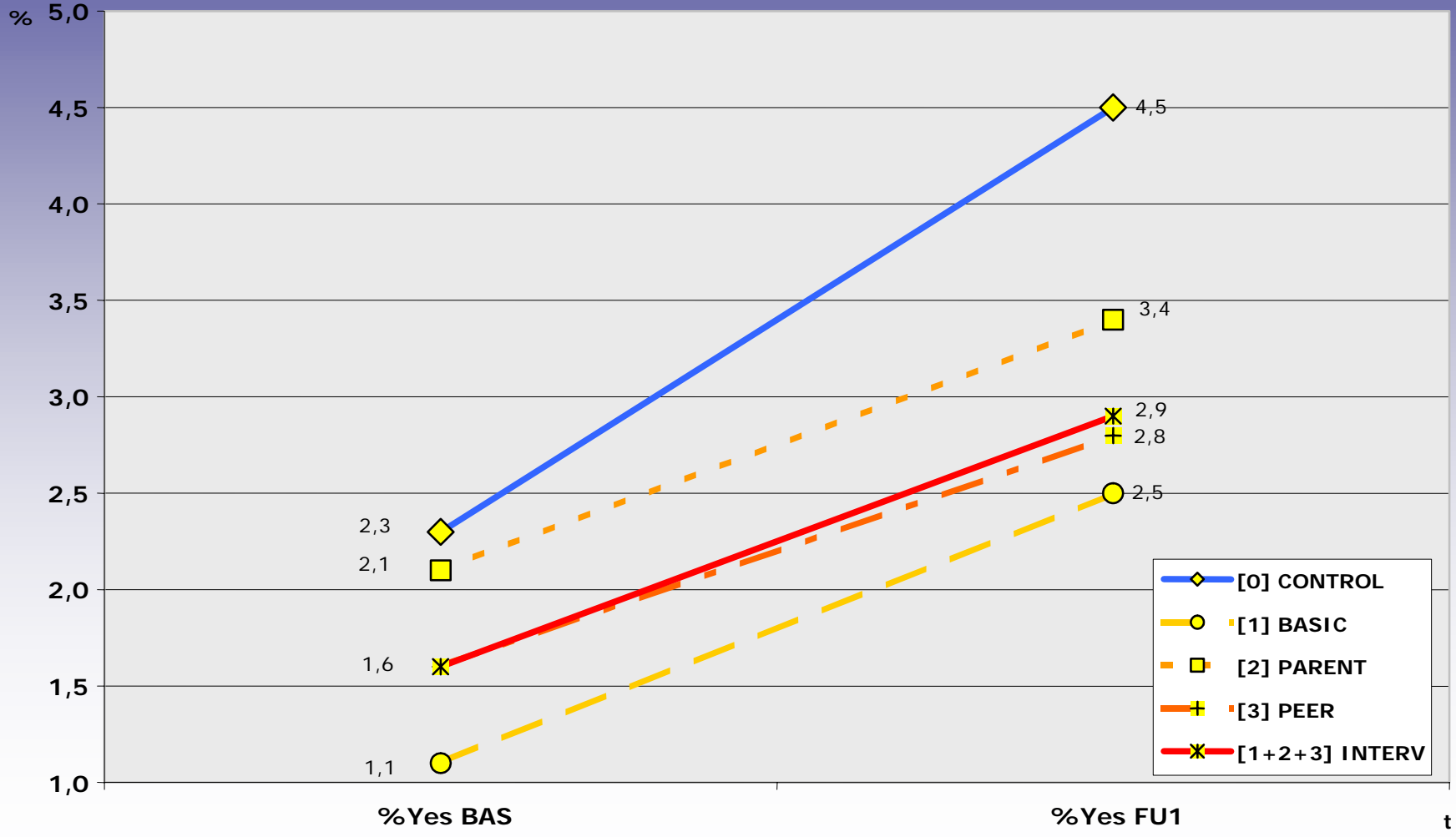


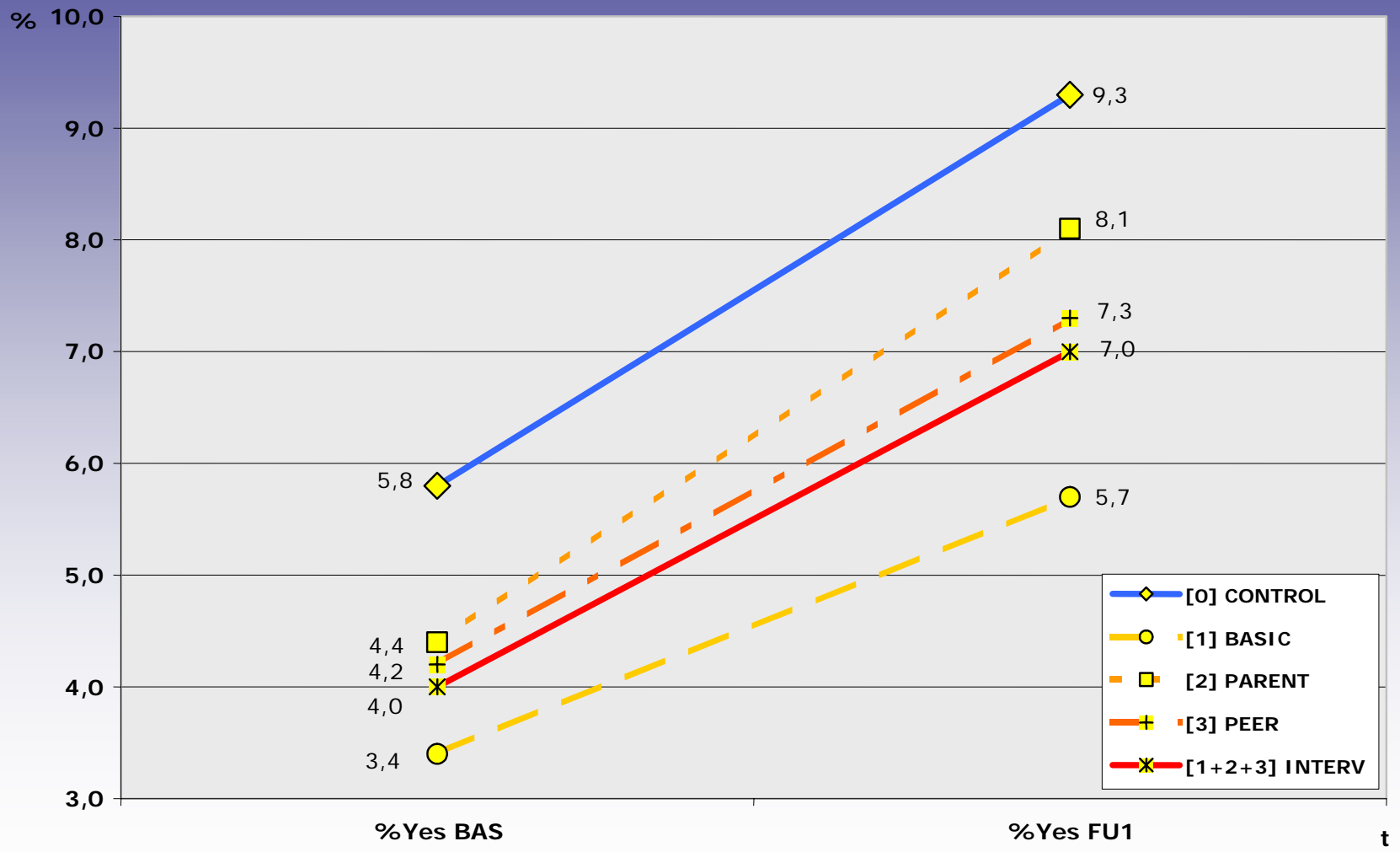
Regular drunkenness





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)

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

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

- The statistical analysis shows that ***Unplugged*** is effective in reducing use of drugs, alcohol and cigarettes at the first follow-up
- It is the ***first european program*** evaluated through a multicentric, randomized controlled trial design