Santander, 10-11 July 2006

Evaluation in substance abuse prevention

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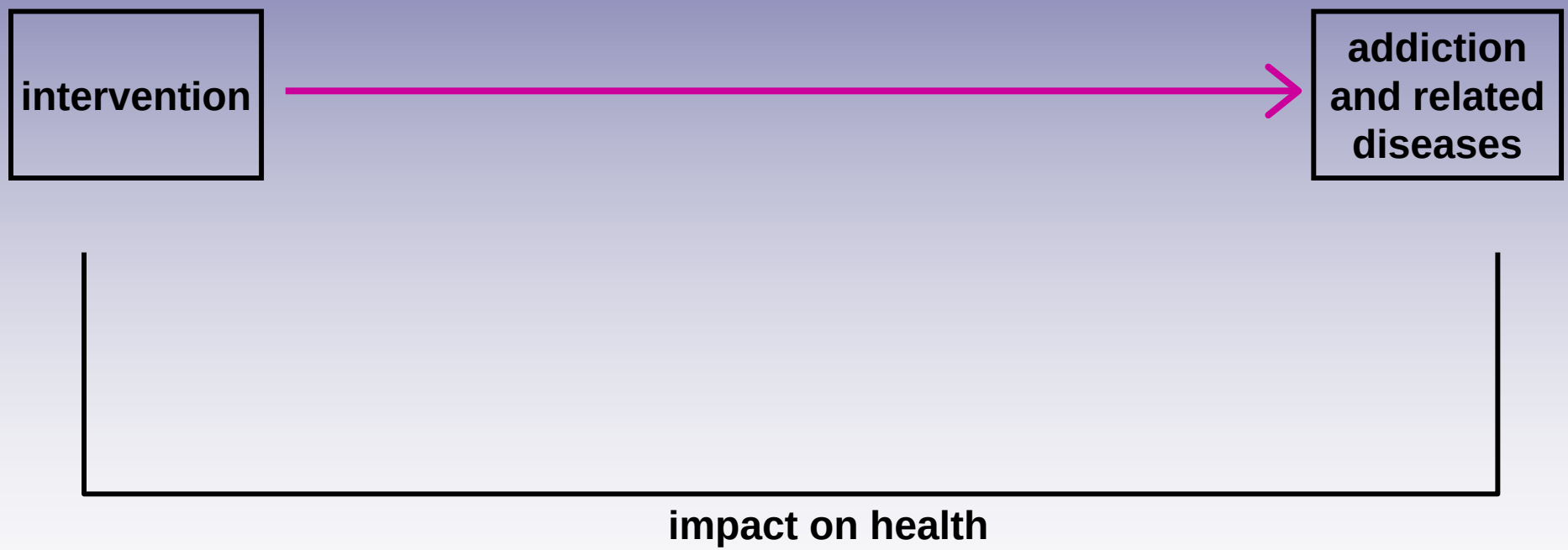
Difficulties of the evaluation

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

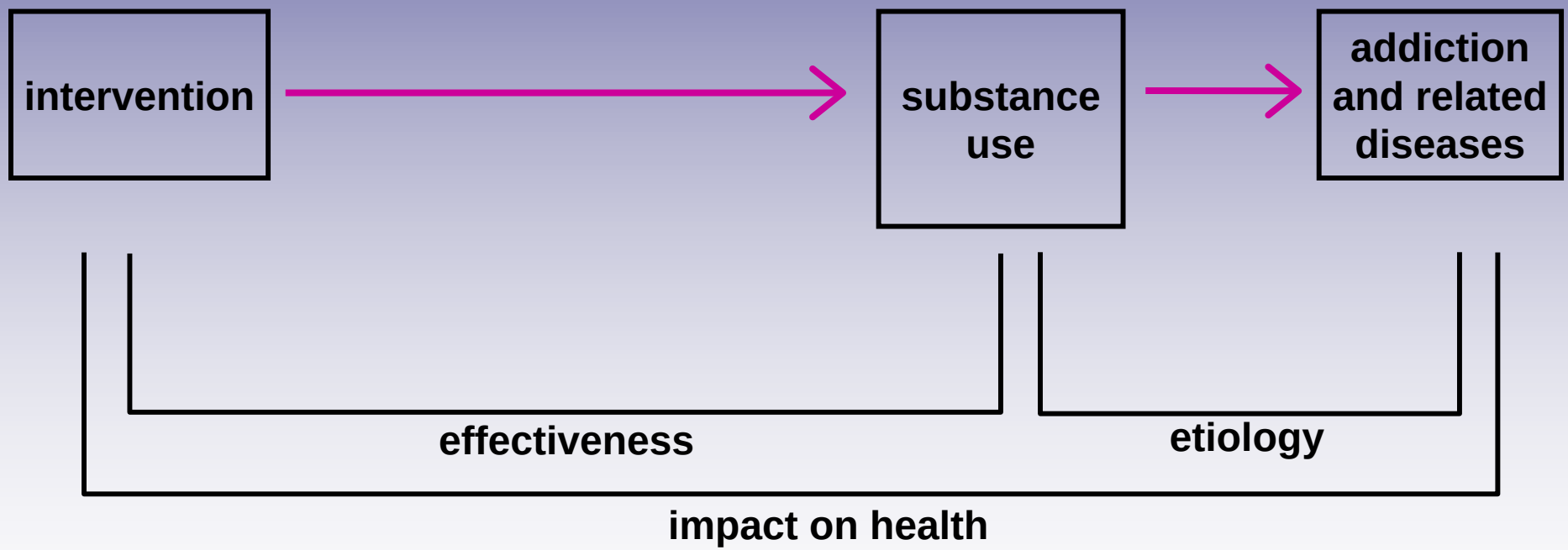
Levels of evaluation in substance use prevention (I)



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

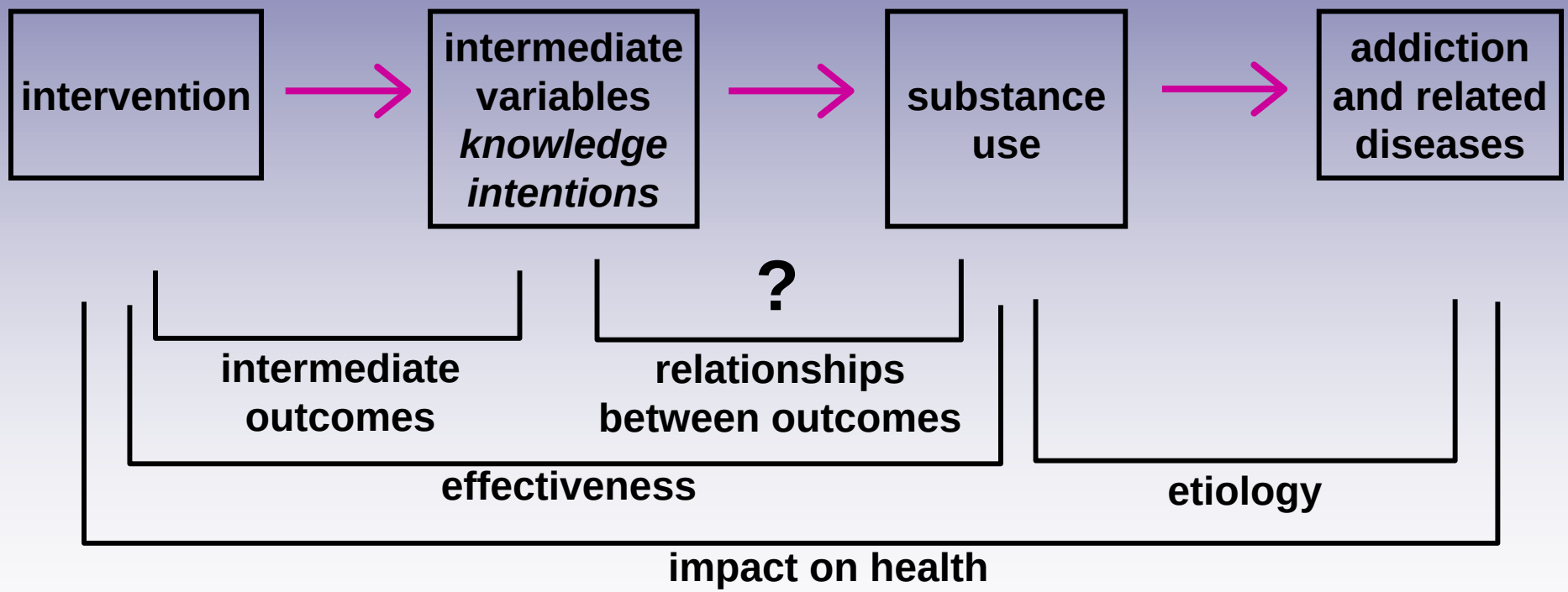
Levels of evaluation in substance use prevention (II)



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 institues 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 institues must design and conduct this kind of studies
- **Current state of research**: quite delayed

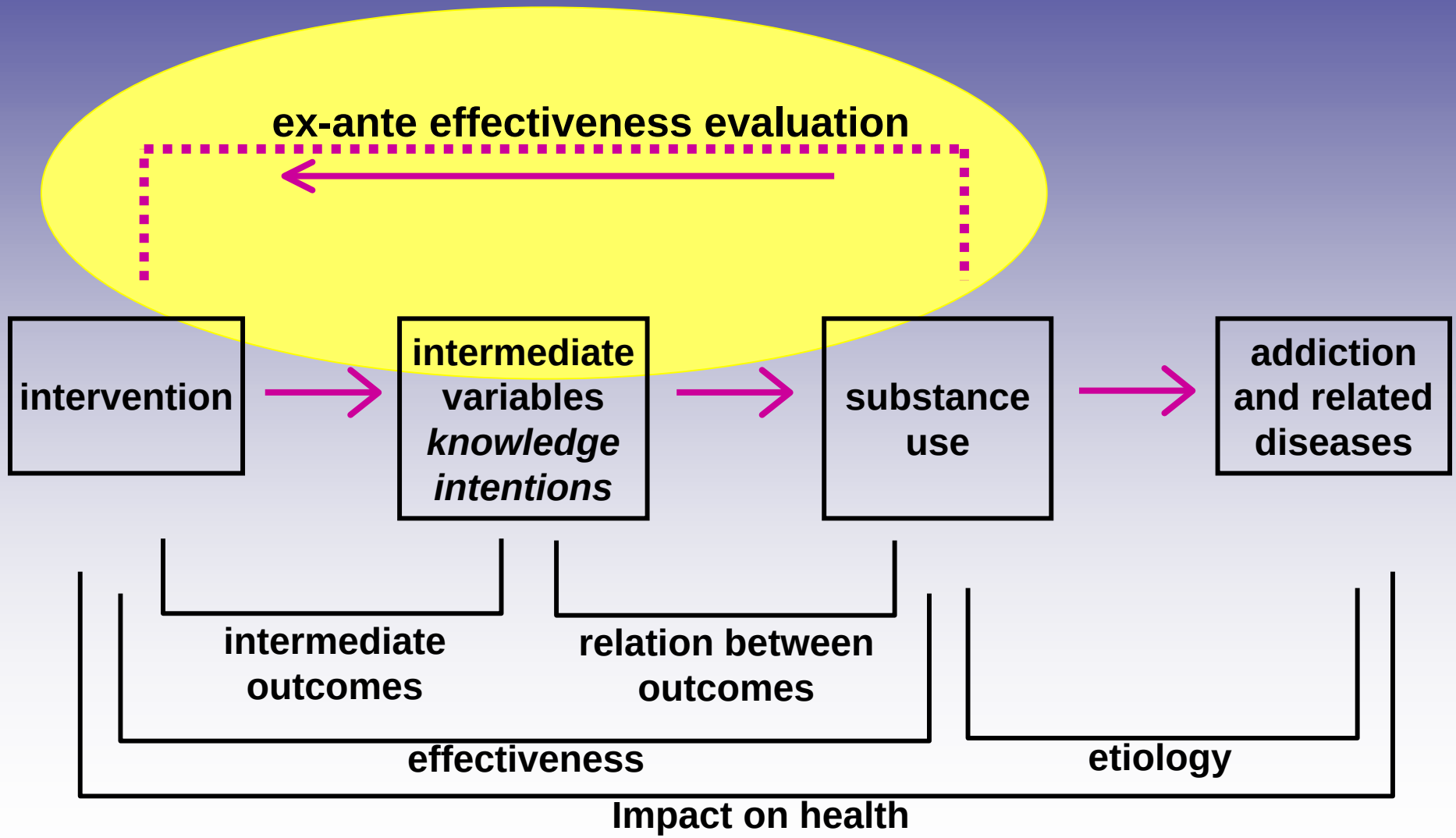
Responsibility of evaluation

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

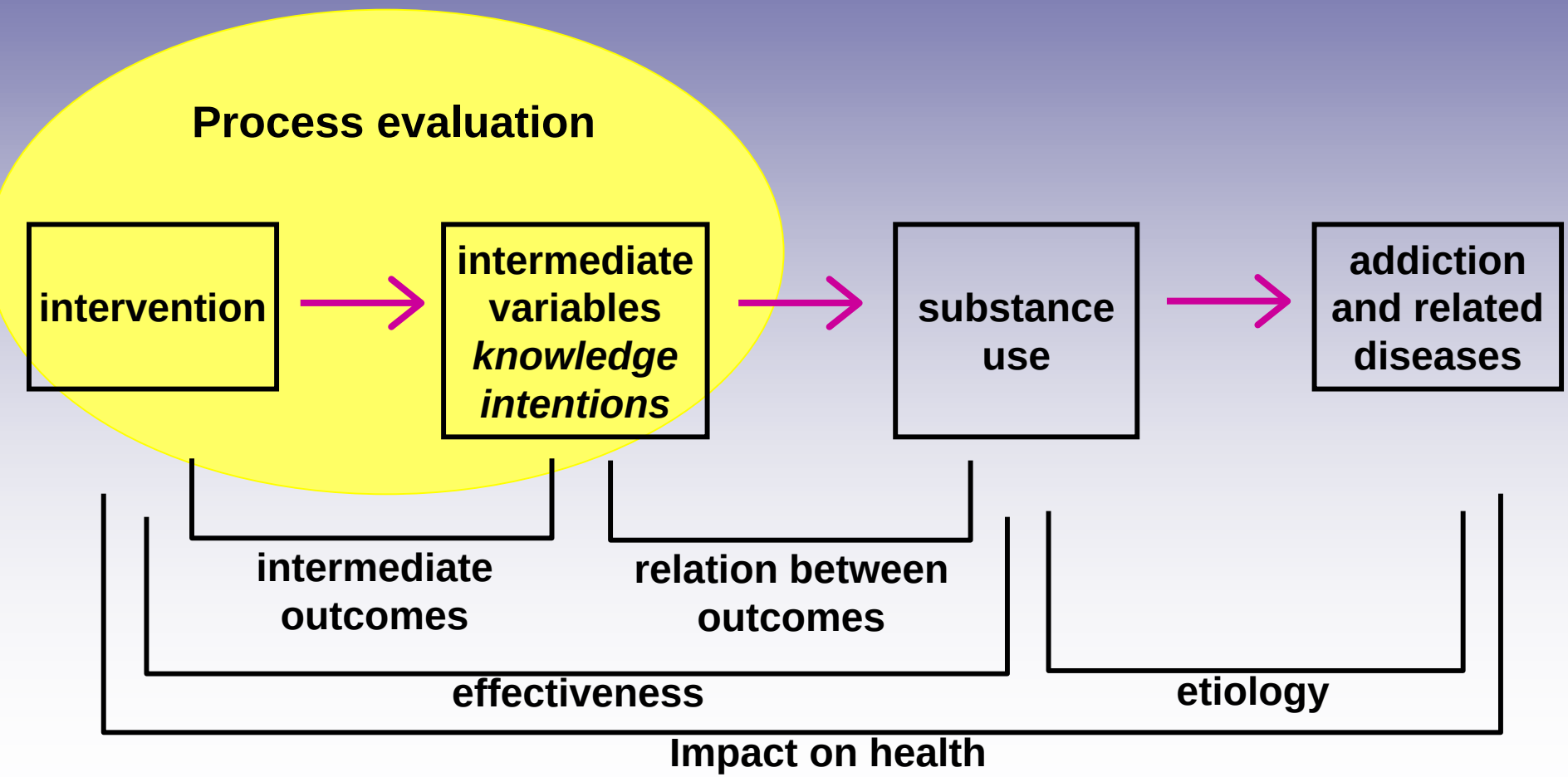
Responsibility for practitioners

- **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)



Levels of evaluation in substance use prevention (V)



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**

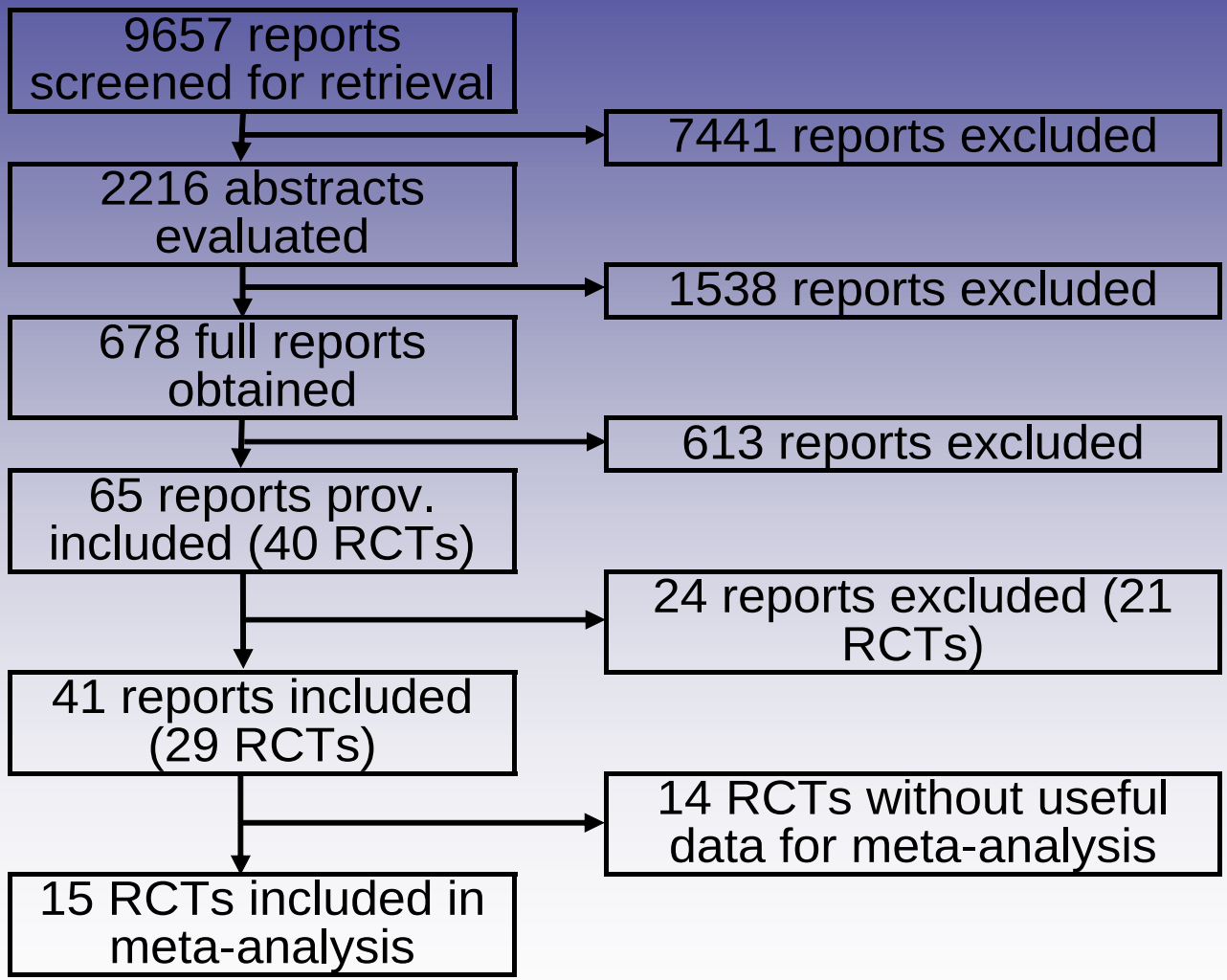
in a **school setting**

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

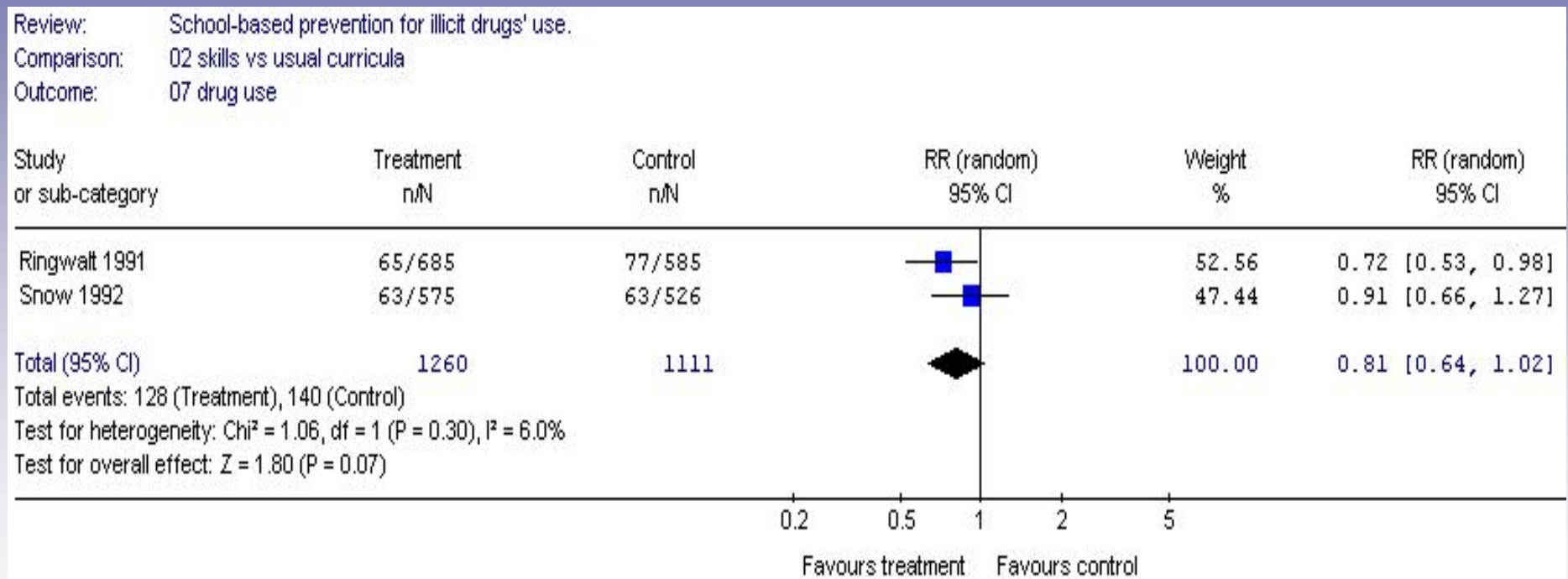
Methods: Statistical analysis

- 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)

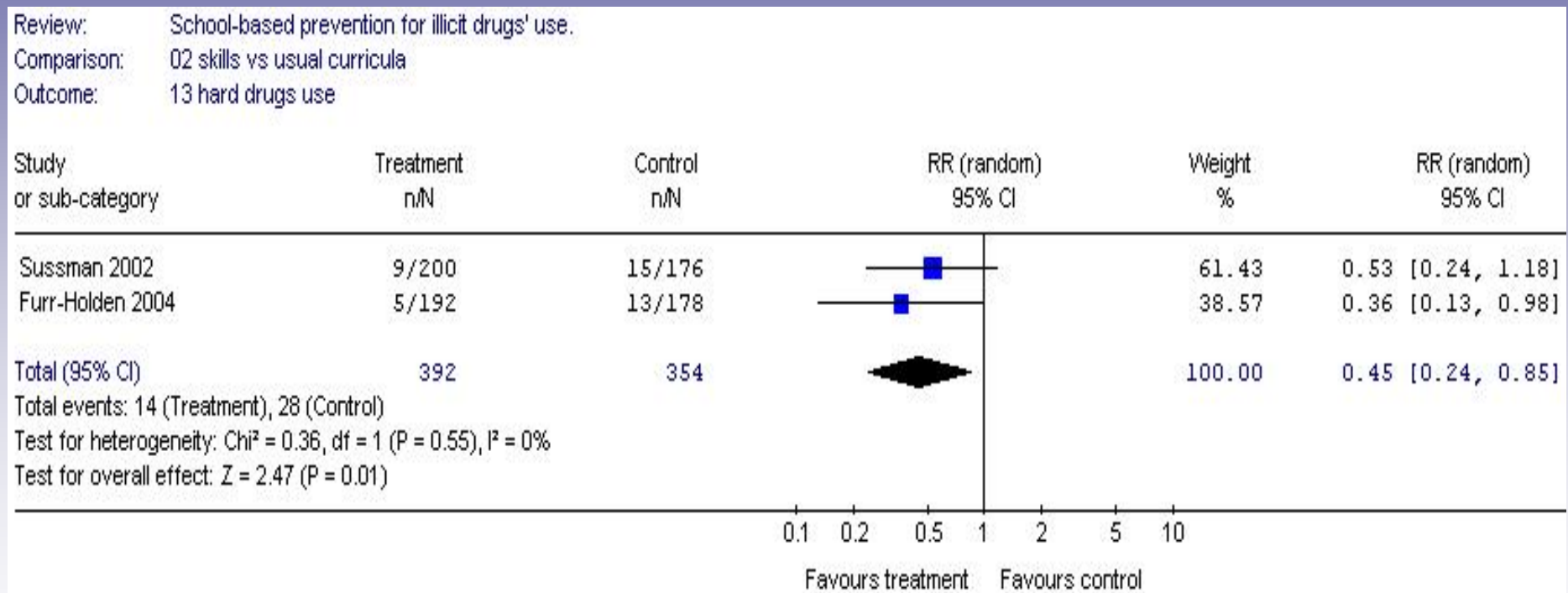
Included studies

- **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

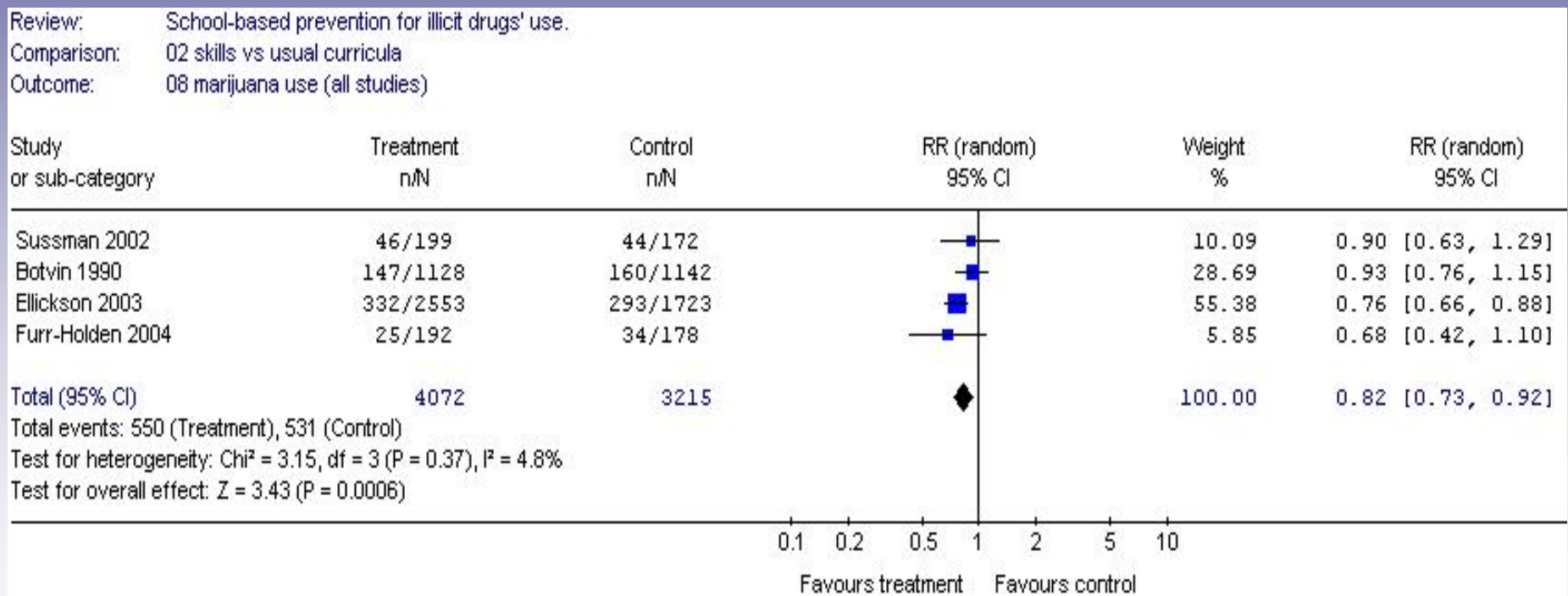
Results
Skills versus usual curricula
drugs use



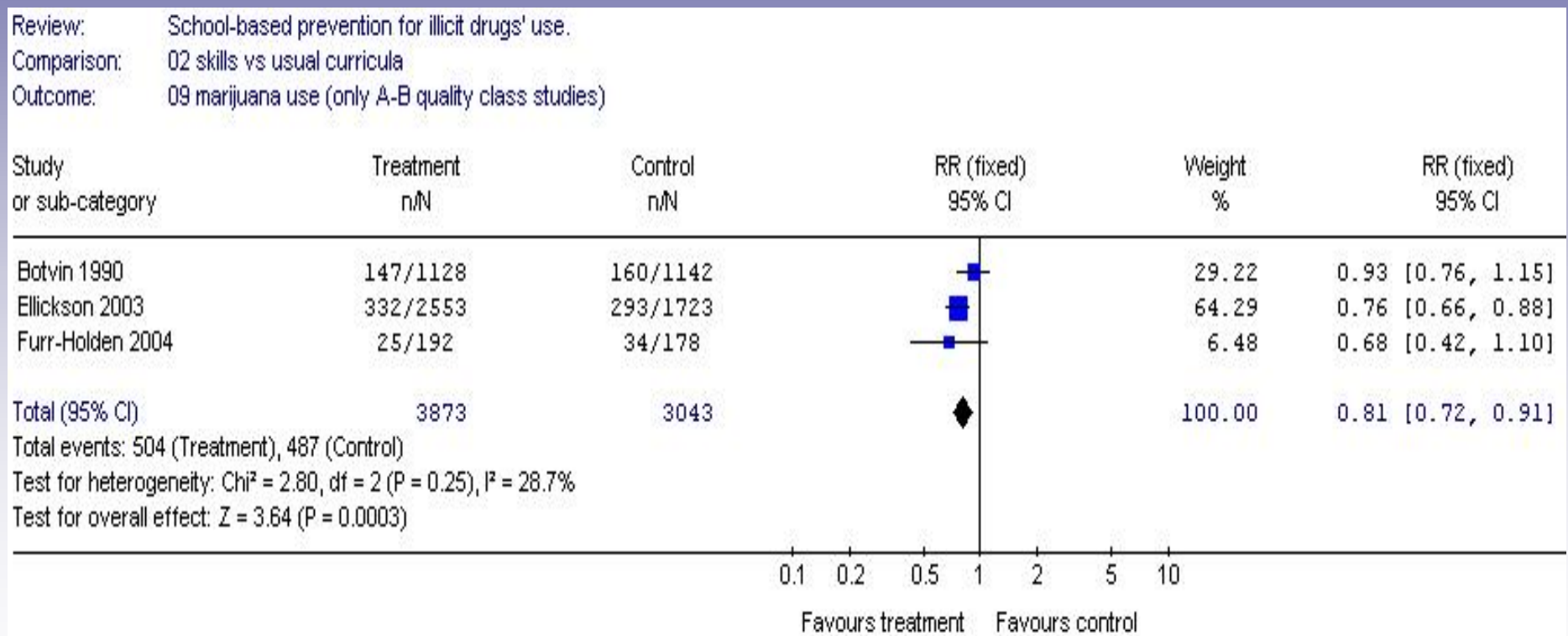
Results
Skills versus usual curricula
hard drugs use



Results
Skills versus usual curricula
marijuana use



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

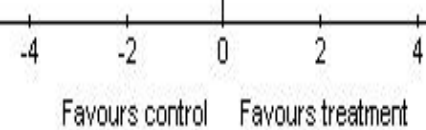


Results
Skills versus usual curricula
decision making skills

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

Study or sub-category	Treatment N	Treatment Mean (SD)	Control N	Control Mean (SD)	SMD (random) 95% CI	Weight %	SMD (random) 95% CI
Snow 1992	581	36.29 (7.02)	528	30.65 (5.36)		64.01	0.90 [0.77, 1.02]
Hurry 1997	65	5.10 (2.40)	55	3.60 (2.90)		35.99	0.56 [0.20, 0.93]
Total (95% CI)	646		583			100.00	0.78 [0.46, 1.09]

Test for heterogeneity: $Chi^2 = 2.84$, df = 1 (P = 0.09), $I^2 = 64.8\%$
Test for overall effect: Z = 4.87 (P < 0.00001)

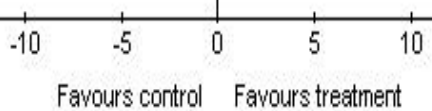


Results
Affective versus usual curricula
drug knowledge

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

Study or sub-category	Treatment N	Treatment Mean (SD)	Control N	Control Mean (SD)	SMD (random) 95% CI	Weight %	SMD (random) 95% CI
Corbin 1993	22	18.23(1.19)	19	12.63(4.57)		71.71	1.70 [0.98, 2.43]
Jones 1995	14	18.14(1.41)	8	12.50(3.42)		28.29	2.34 [1.18, 3.49]
Total (95% CI)	36		27			100.00	1.88 [1.27, 2.50]

Test for heterogeneity: Chi² = 0.83, df = 1 (P = 0.36), I² = 0%
Test for overall effect: Z = 6.00 (P < 0.00001)

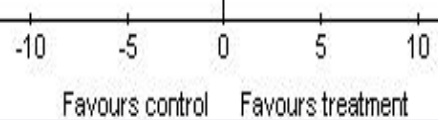


Results
Affective versus usual curricula
decision making skills

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

Study or sub-category	Treatment N	Treatment Mean (SD)	Control N	Control Mean (SD)	SMD (random) 95% CI	Weight %	SMD (random) 95% CI
Corbin 1993	22	8.18(1.14)	19	6.26(1.73)		67.73	1.31 [0.62, 1.99]
Jones 1995	14	7.29(1.44)	8	5.12(1.46)		32.27	1.44 [0.45, 2.43]
Total (95% CI)	36		27			100.00	1.35 [0.79, 1.91]

Test for heterogeneity: $Chi^2 = 0.05$, $df = 1$ ($P = 0.82$), $I^2 = 0\%$
Test for overall effect: $Z = 4.71$ ($P < 0.00001$)

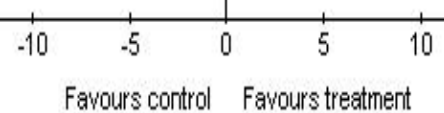


Results
Knowledge versus usual curricula
drug knowledge

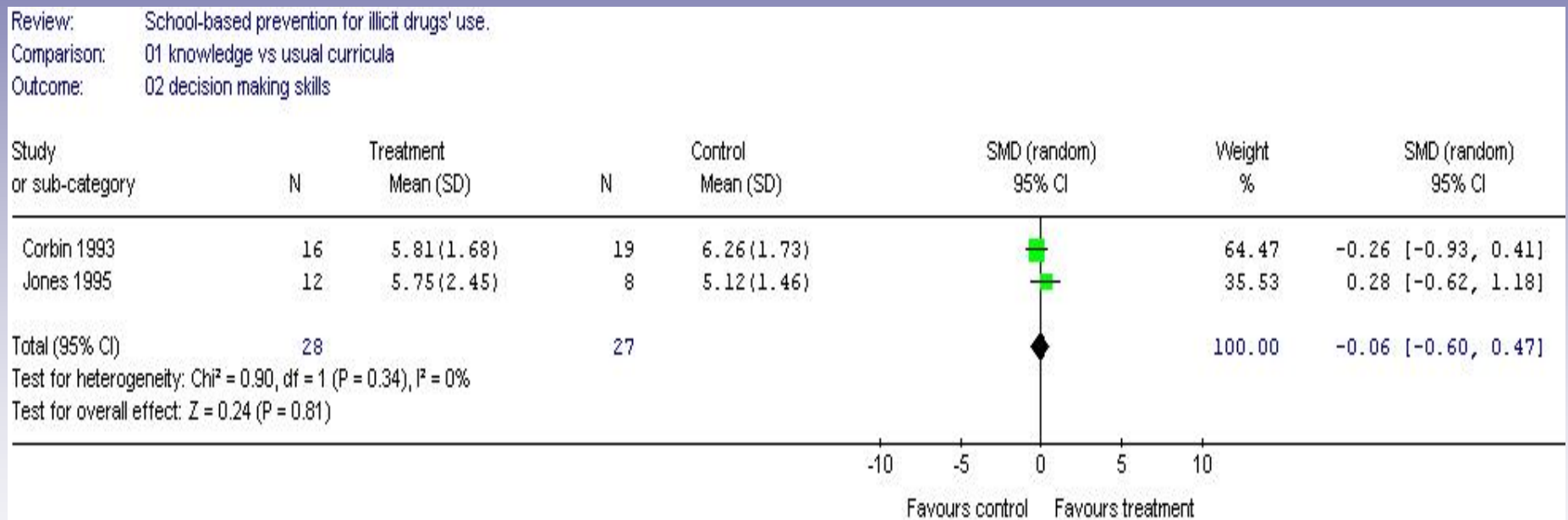
Review: School-based prevention for illicit drugs' use.
Comparison: 01 knowledge vs usual curricula
Outcome: 01 drug knowledge

Study or sub-category	Treatment N	Treatment Mean (SD)	Control N	Control Mean (SD)	SMD (random) 95% CI	Weight %	SMD (random) 95% CI
Corbin 1993	16	17.06(2.86)	19	12.63(4.57)		27.76	1.11 [0.39, 1.83]
Jones 1995	12	17.00(2.52)	8	12.50(3.42)		16.87	1.48 [0.45, 2.52]
Sigelman 2003	86	0.91(0.11)	79	0.81(0.20)		55.37	0.62 [0.31, 0.94]
Total (95% CI)	114		106			100.00	0.91 [0.42, 1.39]

Test for heterogeneity: Chi² = 3.55, df = 2 (P = 0.17), I² = 43.6%
Test for overall effect: Z = 3.66 (P = 0.0002)



Results
Knowledge versus usual curricula
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

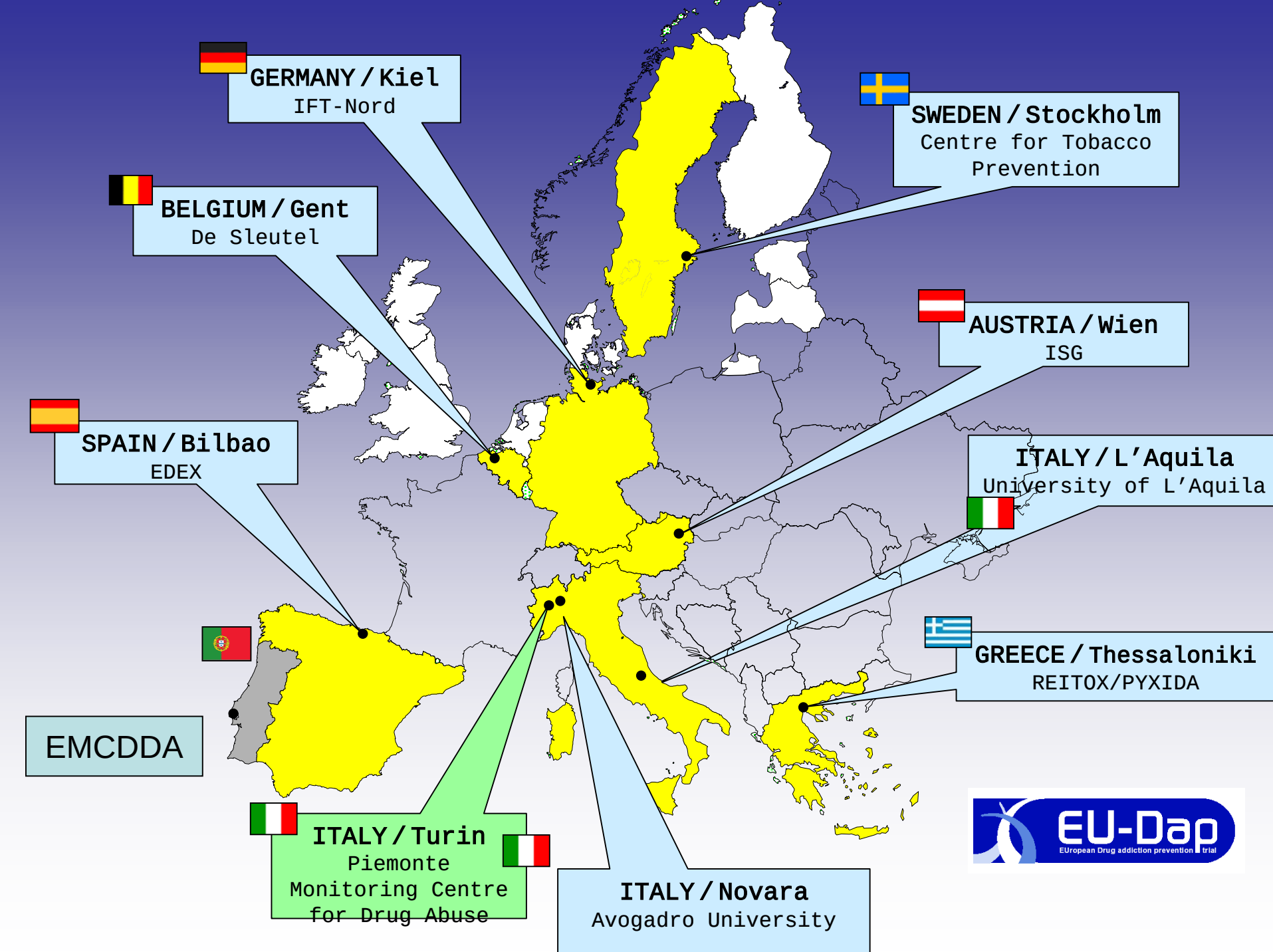
Studio EU-Dap

European Drug Addiction Prevention trial

EU-Dap
EUropean Drug addiction prevention trial

Characteristics

- 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
GREECE / Thessaloniki
REITOX/PYXIDA
EMCDDA
ITALY / Turin
Piemonte Monitoring Centre for Drug Abuse
ITALY / Novara
Avogadro University
EU-Dap
EUropean Drug addiction prevention trial

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"Unplugged"

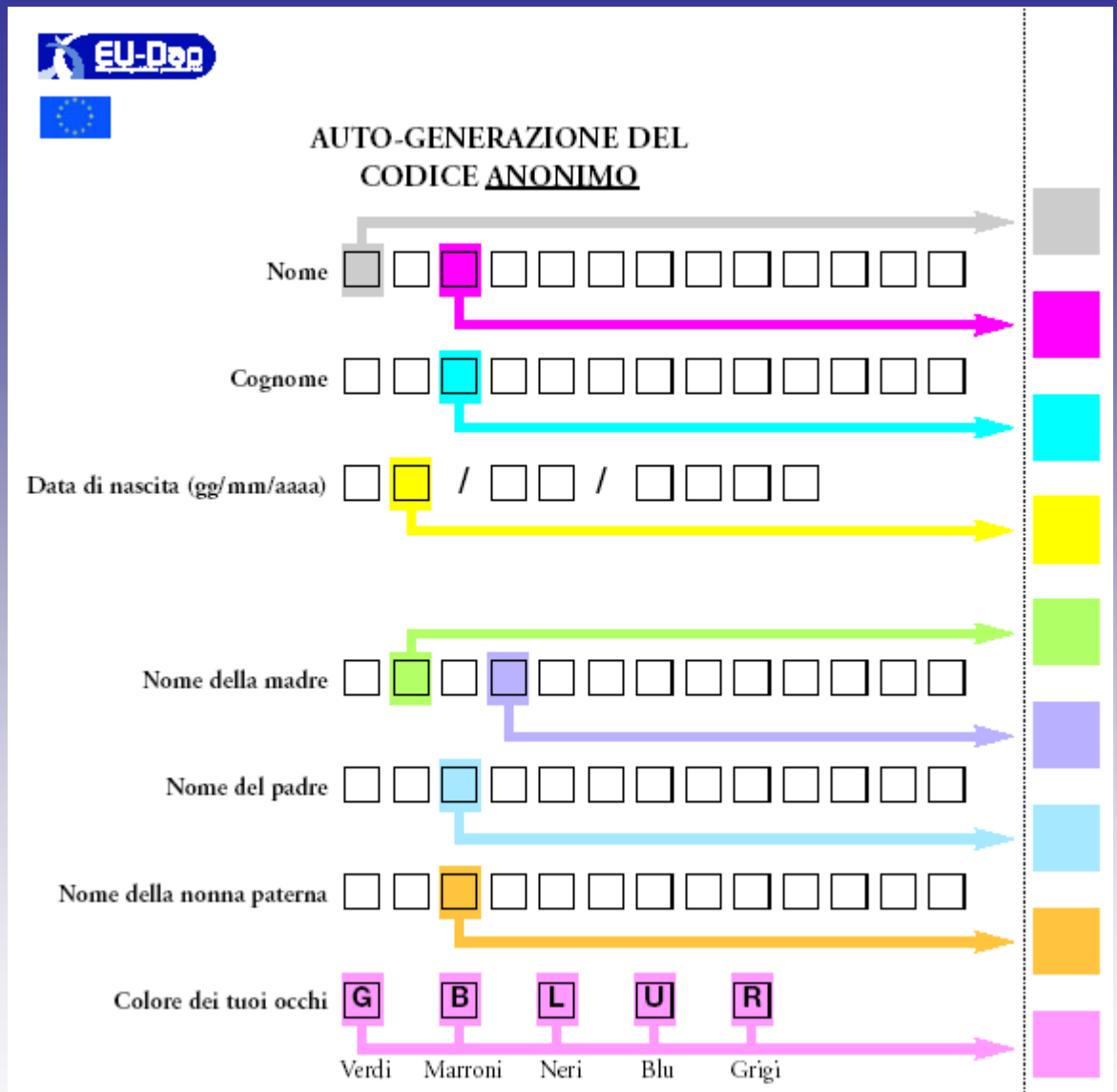
- the program is based on a ***comprehensive social influence approach***
- It includes the following components
  - Social skills
  - Personal skills
  - Knowledge
  - Normative education
  - (No resistance education)
- It is administred by teachers, who participated to a 3 days specific workshop
- It is made by 12 units, 1 hour each

EU-Dap
EUropean Drug addiction prevention trial

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

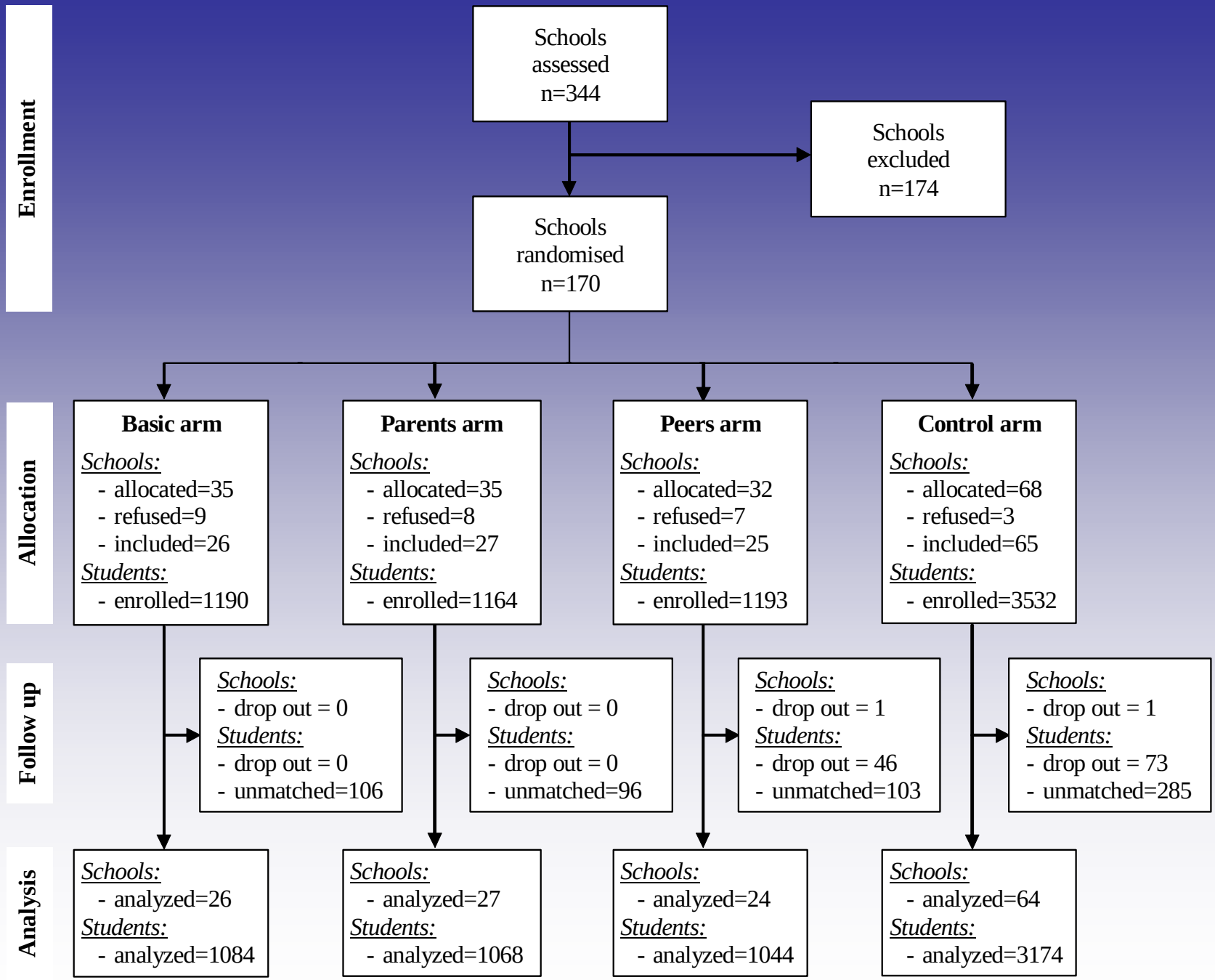


Questionnaire

EU-Dap
EUropean Drug addiction prevention trial

Enrollment

- 7079 students participated in the ***baseline survey*** (November 2004)
- The program (“Unplugged") was administerd 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%

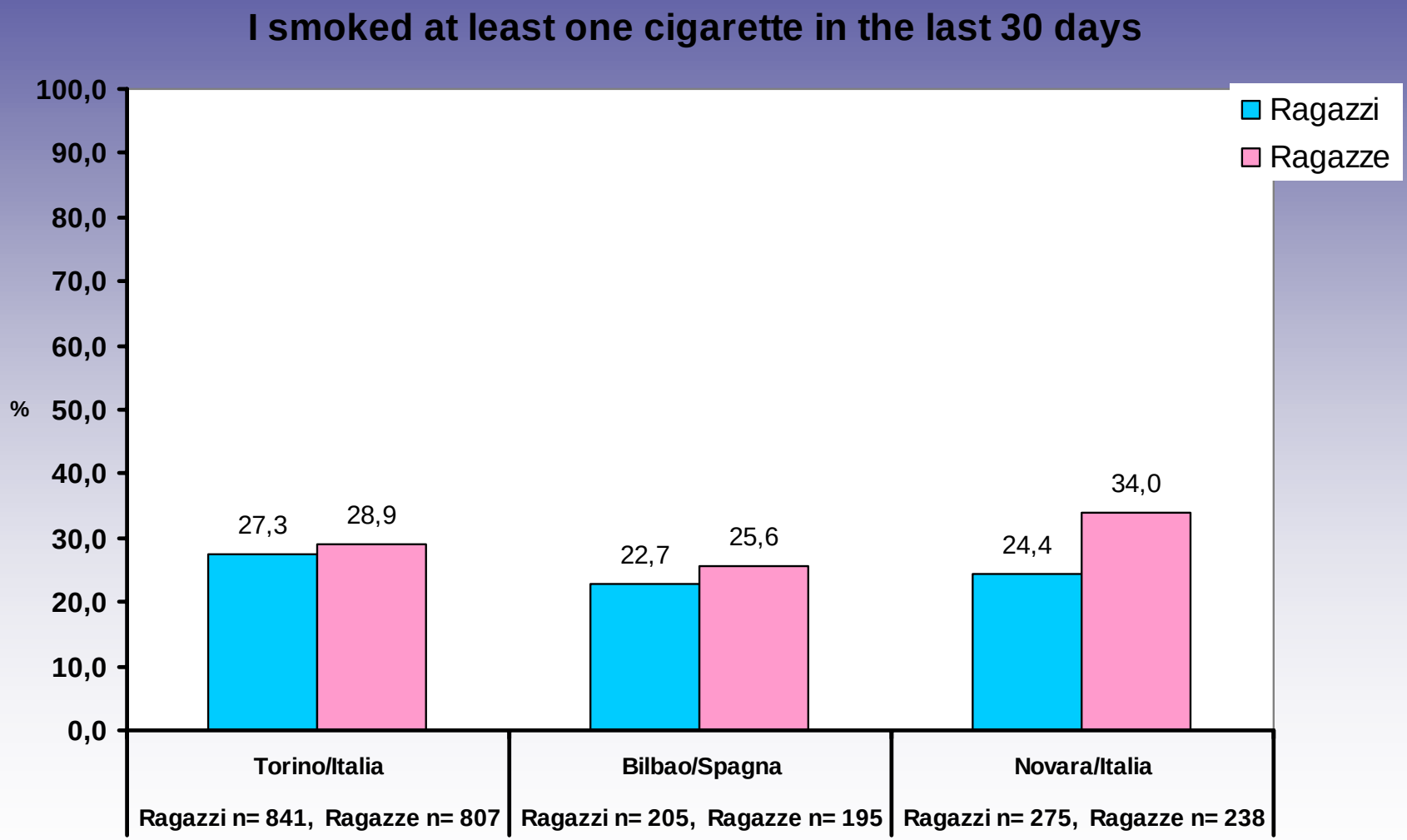

Enrollment
Schools assessed n=344
Schools excluded n=174
Schools randomised n=170
Allocation
Basic arm
Schools:
- allocated=35
- refused=9
- included=26
Students:
- enrolled=1190
Parents arm
Schools:
- allocated=35
- refused=8
- included=27
Students:
- enrolled=1164
Peers arm
Schools:
- allocated=32
- 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

EU-Dap
EUropean Drug addiction prevention trial

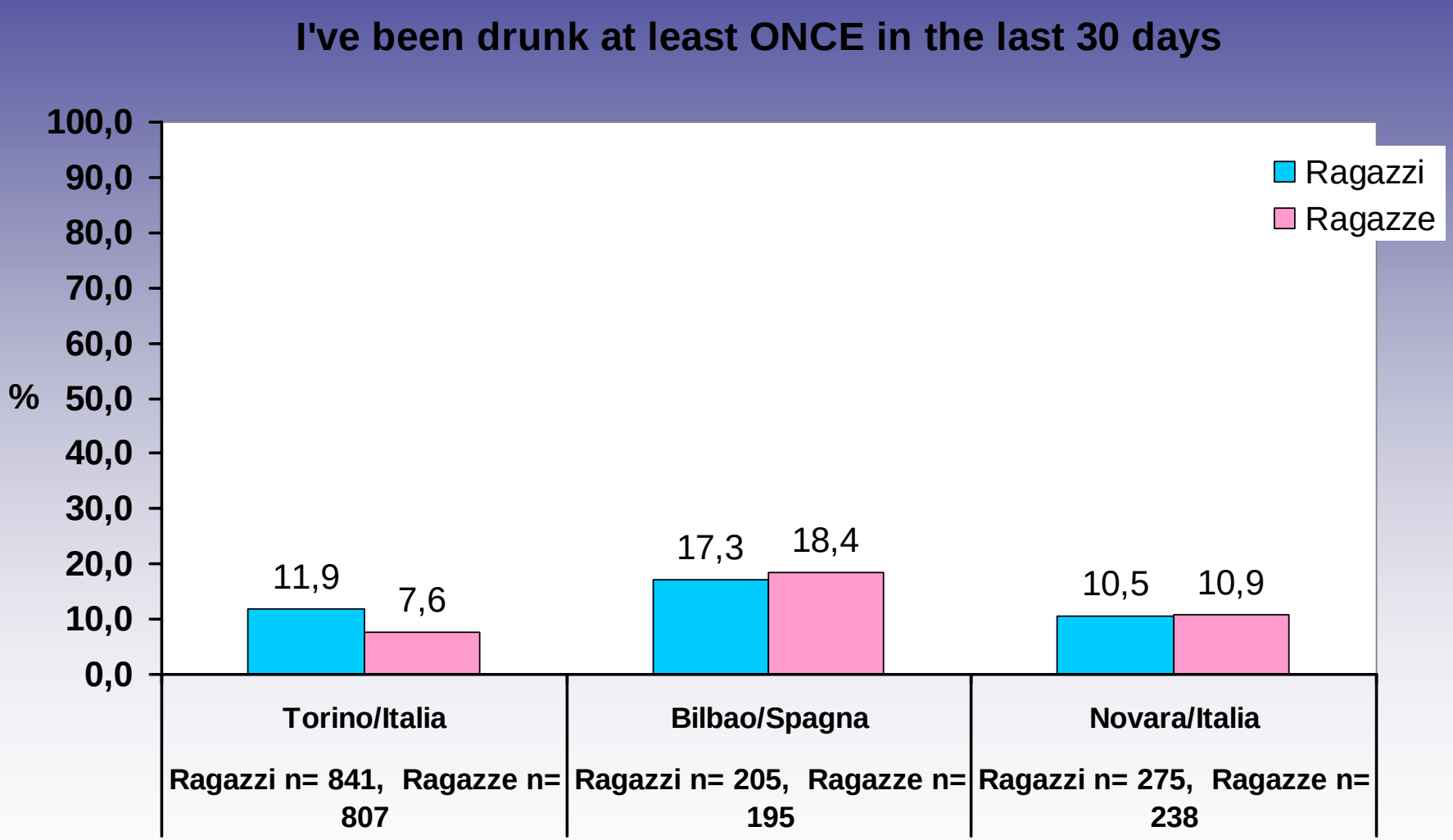
Population

	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

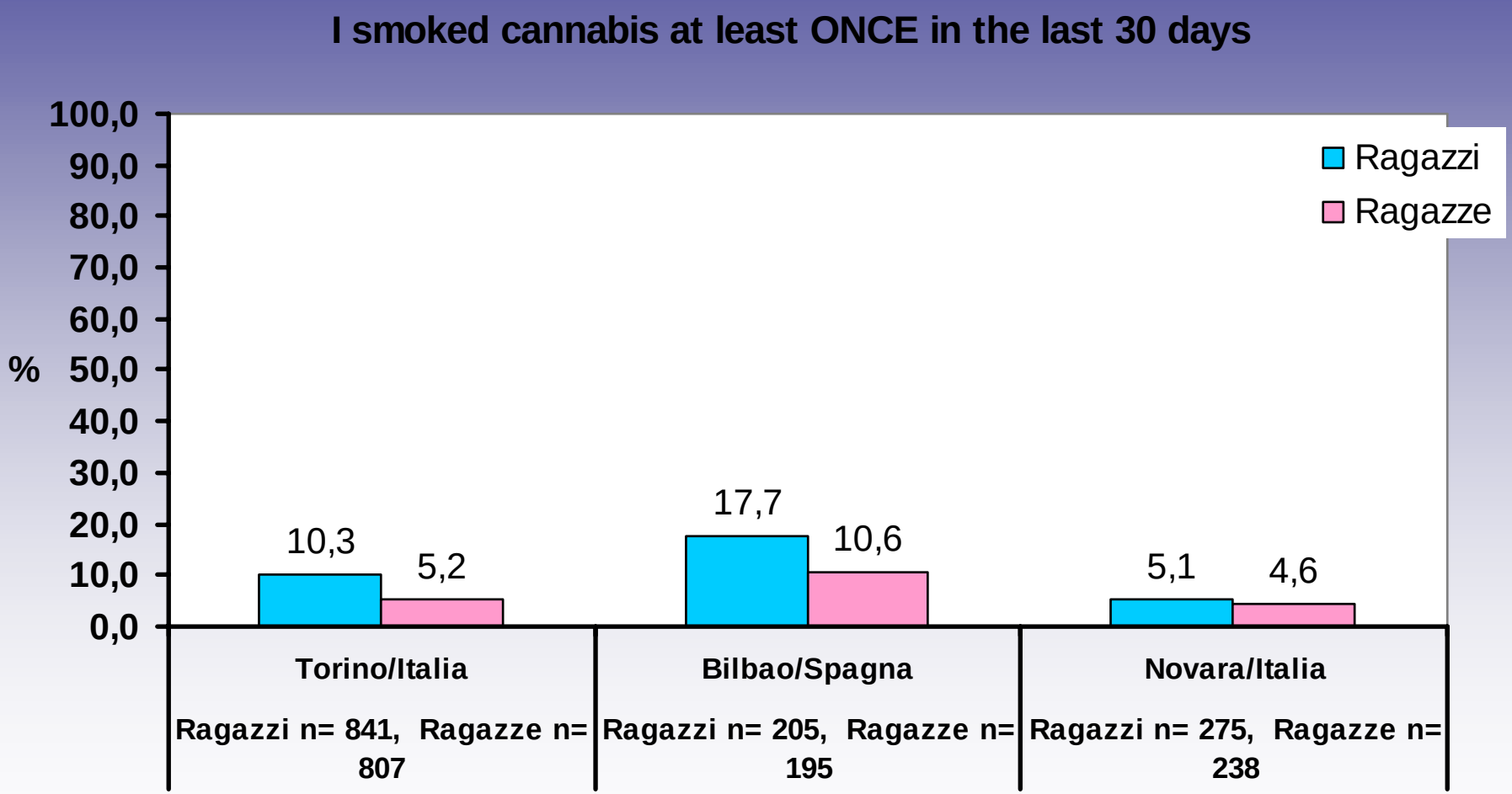
Smoking cigarettes



Have been drunk



Smoking cannabis



EU-Dap
EUropean Drug addiction prevention trial

Measures of effect

- ***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 drukenness***: At least once in the last 30 days
- ***Regular drunkeness***: 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)

EU-Dap
EUropean Drug addiction prevention trial

ALO smoking