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

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for the EU-Dap Coordinating Group
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 schoolchildren, 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
1. School-based prevention for illicit drugs' use

**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 the effectiveness of health technologies using standardised methodologies.

  Cochrane Library (www.cochrane.org)
1. School-based prevention for illicit drugs' use

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• To discover unpublished researches/results, research teams, and 18 authors of studies were contacted
1. School-based prevention for illicit drugs' use

Flow-chart of considered studies

- 9657 reports identified
  - 7441 reports excluded
- 2216 abstracts evaluated
  - 1538 reports excluded
- 678 full texts obtained
  - 613 reports excluded
    - 374: methodological reasons
    - 128: reviews
    - 76: community programs
    - 35: alcohol focused programs
- 65 reports prov. incl. (40 RCTs)
  - 24 reports excluded (21 RCTs)
- 41 reports included (29 RCTs)
- 15 RCTs with useful data
  - 14 RCTs no useful data
1. School-based prevention for illicit drugs' use

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*
1. School-based prevention for illicit drugs’ use

**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

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

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 2/2006)
Comparison: 02 skills vs usual curricula
Outcome: 13 hard drugs use

<table>
<thead>
<tr>
<th>Study or sub-category</th>
<th>Treatment n/N</th>
<th>Control n/N</th>
<th>RR (random) 95% CI</th>
<th>Weight %</th>
<th>RR (random) 95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sussman 2002</td>
<td>9/200</td>
<td>15/176</td>
<td>61.43 [0.24, 1.18]</td>
<td>61.43</td>
<td>0.53 [0.24, 1.18]</td>
</tr>
<tr>
<td>Furr-Holden 2004</td>
<td>5/192</td>
<td>13/178</td>
<td>38.57 [0.13, 0.98]</td>
<td>38.57</td>
<td>0.36 [0.13, 0.98]</td>
</tr>
</tbody>
</table>

Total (95% CI)

Total events: 14 (Treatment), 28 (Control)
Test for heterogeneity: \( \chi^2 = 0.36, \text{df} = 1 (P = 0.55), I^2 = 0\%
Test for overall effect: \( Z = 2.47 (P = 0.012) \)
School-based prevention for illicit drugs' use

Results

Skills versus usual curricula

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

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)
1. School-based prevention for illicit drugs' use

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)
1. School-based prevention for illicit drugs' use

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
1. School-based prevention for illicit drugs' use

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
2. the EU-Dap Study

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
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
2. the EU-Dap Study

Study design

- The aim of “Unplugged” is to prevent or delay the onset of tobacco and drugs use, and of alcohol misuse.

- To evaluate its effectiveness EU-Dap is a Cluster randomised controlled trial.

- The schools to be included have 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.
2. the EU-Dap Study

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

Schools assessed n=344

Schools randomised n=170

Schools excluded n=174

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

Parents arm  
Schools:  
- allocated=35  
- refused=8  
- included=25  
Students:  
- enrolled=1164

Peers arm  
Schools:  
- allocated=32  
- refused=7  
- included=27  
Students:  
- enrolled=1193

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

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

Allocation

Enrollment

Follow up

Analysis

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

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

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

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

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

<table>
<thead>
<tr>
<th></th>
<th>Boy (N=3680)</th>
<th>Girl (N=3288)</th>
<th>Total (N=7079)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>ALO smoked cigarettes</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>%</td>
<td>14.2</td>
<td>16.9</td>
<td>15.5</td>
</tr>
<tr>
<td>N</td>
<td>497</td>
<td>537</td>
<td>1034</td>
</tr>
<tr>
<td></td>
<td>218</td>
<td>208</td>
<td>426</td>
</tr>
<tr>
<td><strong>ALO drunkenness</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>%</td>
<td>7.3</td>
<td>6.0</td>
<td>6.7</td>
</tr>
<tr>
<td>N</td>
<td>260</td>
<td>194</td>
<td>454</td>
</tr>
<tr>
<td></td>
<td>83</td>
<td>57</td>
<td>140</td>
</tr>
<tr>
<td><strong>ALO smoked cannabis</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>%</td>
<td>4.7</td>
<td>2.8</td>
<td>3.8</td>
</tr>
<tr>
<td>N</td>
<td>169</td>
<td>92</td>
<td>261</td>
</tr>
<tr>
<td></td>
<td>110</td>
<td>47</td>
<td>157</td>
</tr>
<tr>
<td><strong>ALO drugs use</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>%</td>
<td>6.1</td>
<td>4.6</td>
<td>5.4</td>
</tr>
<tr>
<td>N</td>
<td>223</td>
<td>150</td>
<td>373</td>
</tr>
</tbody>
</table>
2. the EU-Dap Study

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

<table>
<thead>
<tr>
<th></th>
<th>Parents Not Smoking (N=3042)</th>
<th>One Parent Smoking (N=2396)</th>
<th>Both Parents Smoking (N=1554)</th>
<th>Siblings Not Smoking (N=4847)</th>
<th>Siblings Smoking (N=1276)</th>
<th>Total (N=7079)</th>
</tr>
</thead>
<tbody>
<tr>
<td>ALO smoked cigarettes</td>
<td>% 28.3 (N=857)</td>
<td>38.2 (N=910)</td>
<td>43.1 (N=663)</td>
<td>28.0 (N=1348)</td>
<td>59.1 (N=744)</td>
<td>35.0 (N=2442)</td>
</tr>
</tbody>
</table>
Effect of the parent’s permission to smoke or to be drunk

<table>
<thead>
<tr>
<th></th>
<th>Would allow (N=1091)</th>
<th>Wouldn't allow (N=5169)</th>
<th>Don’t know (N=690)</th>
<th>Total (N=7079)</th>
</tr>
</thead>
<tbody>
<tr>
<td>ALO smoked cigarettes</td>
<td>% 61.0</td>
<td>% 29.3</td>
<td>% 36.8</td>
<td>% 35.1</td>
</tr>
<tr>
<td></td>
<td>N 663</td>
<td>N 1506</td>
<td>N 251</td>
<td>N 2420</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>% 43.8</th>
<th>% 16.6</th>
<th>% 26.0</th>
<th>% 24.2</th>
</tr>
</thead>
<tbody>
<tr>
<td>ALO drunkenness</td>
<td>N 640</td>
<td>N 680</td>
<td>N 345</td>
<td>N 1665</td>
</tr>
</tbody>
</table>
## Characteristics of the analysis sample

<table>
<thead>
<tr>
<th>Gender</th>
<th>Controls (N=3297)</th>
<th>All interventions (N=3307)</th>
<th>Total population (N=6604)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n</td>
<td>%</td>
<td>n</td>
</tr>
<tr>
<td>boys</td>
<td>1629</td>
<td>51.3</td>
<td>1695</td>
</tr>
<tr>
<td>girls</td>
<td>1538</td>
<td>48.5</td>
<td>1497</td>
</tr>
<tr>
<td>missing</td>
<td>7</td>
<td>0.2</td>
<td>4</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Age</th>
<th>Controls (N=3297)</th>
<th>All interventions (N=3307)</th>
<th>Total population (N=6604)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n</td>
<td>%</td>
<td>n</td>
</tr>
<tr>
<td>12 years</td>
<td>1043</td>
<td>32.9</td>
<td>998</td>
</tr>
<tr>
<td>13 years</td>
<td>851</td>
<td>26.8</td>
<td>1135</td>
</tr>
<tr>
<td>14 years</td>
<td>1280</td>
<td>40.3</td>
<td>1063</td>
</tr>
</tbody>
</table>
### Characteristics of the analysis sample

<table>
<thead>
<tr>
<th>School Grade</th>
<th>Controls (N=3297)</th>
<th>All interventions (N=3307)</th>
<th>Total population (N=6604)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n</td>
<td>%</td>
<td>n</td>
</tr>
<tr>
<td>7th level</td>
<td>1469</td>
<td>46.3</td>
<td>1499</td>
</tr>
<tr>
<td>8th level</td>
<td>425</td>
<td>13.4</td>
<td>634</td>
</tr>
<tr>
<td>9th level</td>
<td>1280</td>
<td>40.3</td>
<td>1063</td>
</tr>
</tbody>
</table>
## Characteristics of the analysis sample

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

2. the EU-Dap Study
Effect measure: prevalence

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

Outcomes measures

1. **ALO smoking** = at least one cigarette 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 drunkenness** = at least once in last 30d
5. **Regular drunkenness** = 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)

- [0] CONTROL
- [1] BASIC
- [2] PARENT
- [3] PEER
- [1+2+3] INTERV
2. the EU-Dap Study

Changes in prevalence of drunkenness
(regular drunkenness in last 30 days)
2. the EU-Dap Study

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

<table>
<thead>
<tr>
<th></th>
<th>Controls All subjects</th>
<th>All interventions</th>
<th>p</th>
<th>APR</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>users F-U</td>
<td>Prev</td>
<td>PR</td>
<td>users F-U</td>
</tr>
<tr>
<td>ALO smoked cigarettes</td>
<td>3059</td>
<td>642</td>
<td>0.210</td>
<td>1</td>
</tr>
<tr>
<td>Daily use</td>
<td>3059</td>
<td>294</td>
<td>0.096</td>
<td>1</td>
</tr>
<tr>
<td>Regular use</td>
<td>3059</td>
<td>407</td>
<td>0.133</td>
<td>1</td>
</tr>
<tr>
<td>ALO drunkenness</td>
<td>3112</td>
<td>363</td>
<td>0.117</td>
<td>1</td>
</tr>
<tr>
<td>Regular</td>
<td>3112</td>
<td>123</td>
<td>0.040</td>
<td>1</td>
</tr>
<tr>
<td>ALO smoked cannabis</td>
<td>3157</td>
<td>230</td>
<td>0.073</td>
<td>1</td>
</tr>
<tr>
<td>Regular use</td>
<td>3157</td>
<td>141</td>
<td>0.045</td>
<td>1</td>
</tr>
<tr>
<td>All drugs use</td>
<td>3171</td>
<td>294</td>
<td>0.093</td>
<td>1</td>
</tr>
</tbody>
</table>
2. The EU-Dap Study

**Incidence of use**
*(not adjusted for the cluster effect)*

<table>
<thead>
<tr>
<th></th>
<th>Control</th>
<th></th>
<th>All interventions</th>
<th></th>
<th></th>
<th></th>
<th>p</th>
<th>AIR</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>not users</td>
<td>new users</td>
<td>Inc</td>
<td>RR</td>
<td>not users</td>
<td>new users</td>
<td>Inc</td>
<td>RR</td>
</tr>
<tr>
<td><strong>ALO smoked cigarettes</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Daily use</td>
<td>2516</td>
<td>247</td>
<td>0.098</td>
<td>1</td>
<td>2597</td>
<td>224</td>
<td>0.086</td>
<td>0.88</td>
</tr>
<tr>
<td>Regular use</td>
<td>2786</td>
<td>128</td>
<td>0.046</td>
<td>1</td>
<td>2842</td>
<td>76</td>
<td>0.027</td>
<td>0.58</td>
</tr>
<tr>
<td><strong>ALO drunkenness</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Regular</td>
<td>2857</td>
<td>233</td>
<td>0.082</td>
<td>1</td>
<td>2920</td>
<td>174</td>
<td>0.060</td>
<td>0.73</td>
</tr>
<tr>
<td><strong>ALO smoked cannabis</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Regular use</td>
<td>3008</td>
<td>132</td>
<td>0.044</td>
<td>1</td>
<td>3066</td>
<td>93</td>
<td>0.030</td>
<td>0.69</td>
</tr>
<tr>
<td><strong>All drugs use</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>2972</td>
<td>181</td>
<td>0.061</td>
<td>1</td>
<td>3059</td>
<td>151</td>
<td>0.049</td>
<td>0.81</td>
</tr>
</tbody>
</table>
2. the EU-Dap Study

**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)
2. the EU-Dap Study

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.
2. the EU-Dap Study

Multilevel analysis

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

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

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

<table>
<thead>
<tr>
<th>outcome</th>
<th>males</th>
<th>females</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N cntr</td>
<td>N int</td>
</tr>
<tr>
<td>ALO smoking</td>
<td>327/1566</td>
<td>236/1634</td>
</tr>
<tr>
<td>regular smoking</td>
<td>222/1566</td>
<td>133/1634</td>
</tr>
<tr>
<td>daily smoking</td>
<td>167/1566</td>
<td>83/1634</td>
</tr>
<tr>
<td>ALO drunkenness</td>
<td>214/1588</td>
<td>145/1661</td>
</tr>
<tr>
<td>regular drunkenness</td>
<td>83/1588</td>
<td>51/1661</td>
</tr>
<tr>
<td>ALO cannabis</td>
<td>165/1617</td>
<td>91/1686</td>
</tr>
<tr>
<td>regular cannabis</td>
<td>109/1617</td>
<td>56/1686</td>
</tr>
<tr>
<td>ALO drugs</td>
<td>195/1627</td>
<td>116/1691</td>
</tr>
</tbody>
</table>
• **Unplugged** works, at 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

**Discussion of results**
2. the EU-Dap Study

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
2. the EU-Dap Study

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?
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