An effective school-based prevention program for tobacco, alcohol and drugs: 

the EU-Dap cluster randomised trial

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Background

• in developed countries, substance abuse (incl, tobacco and alcohol), accounts for:
  – 20% of all deaths and
  – 22% of YPLL (Single 2000)
• tobacco, alcohol, and illicit drugs share common determinants, natural history, and neurological pathways of abuse liability (McLellan 2000, Di Chiara 2000);
• the incidence of first use increases rapidly from early adolescence (Kandel 1993).
• School is an appropriate setting for drugs use prevention programs
Background

• Cochrane reviews established that programs based on **Social influence approach** have some efficacy in
  – reducing drug use (Faggiano 2005),
  – results for tobacco and alcohol were less convincing (Thomas 2002; Foxcroft 2002):
• more recent studies show effects in delaying smoking onset (Griffin 2002, Crone 2003).

• On the other hand:
  – **some programmes can make harm** (Dukes 1997; Hawthorne 1996)
  – most evaluation studies were carried out in North America or in Australia (**concern for generalisation**).
Methods

• **EU-Dap** is 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”

• is based on a **comprehensive social influence approach**
  – including the following components:
    • social skills
    • personal skills
    • knowledge
    • normative education

• delivered by the class teachers, trained with a 3-days training course

• composed by 12 one-hour units delivered weekly from October 2004 to January 2005
Design of the evaluation

• EU-Dap is a *Cluster randomised controlled trial*
  – schools were randomised
  – students were the unit of analysis

• The schools to be included were selected by chance among all schools of the centre area

• A stratified randomisation was carried out to ensure a balanced sample according to *social status*
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
Schools randomised n=170

Schools assessed n=344

Schools excluded n=174

Schools assessed n=344

Enrollment

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

Allocation

Follow up

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

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

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

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

Analysis

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

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

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

Control arm
Schools: - analyzed=64
Students: - analyzed=3174
• Self completed anonymous questionnaire on use of substances, attitudes, knowledge…
  – most items retrieved from EDDRA data bank
  – identical for all countries
• Linkage between pre- and post-test by a self generated code based on fixed data (some letters from name of parents, date of birth..)
• the reliability was tested in a pilot study (Galanti 2006)
Baseline-followup matching

• 6370 out of 7079 (91.5%) baseline questionnaires matched to the corresponding follow-up questionnaire

  – the matching procedure started using all the 9 digits of the anonymous code, and followed limiting it to 6 digits

  – the last step was a manual linkage, carried independently by 2 researchers, at the level of class
## Characteristics of the analysis sample

<table>
<thead>
<tr>
<th></th>
<th>Study Arm</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Controls (N=3297)</td>
</tr>
<tr>
<td></td>
<td>n</td>
</tr>
<tr>
<td><strong>Gender</strong></td>
<td></td>
</tr>
<tr>
<td>boys</td>
<td>1629</td>
</tr>
<tr>
<td>girls</td>
<td>1538</td>
</tr>
<tr>
<td>missing</td>
<td>7</td>
</tr>
<tr>
<td><strong>Age</strong></td>
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<tr>
<td>12 years</td>
<td>1043</td>
</tr>
<tr>
<td>13 years</td>
<td>851</td>
</tr>
<tr>
<td>14 years</td>
<td>1280</td>
</tr>
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</table>
## Characteristics of the analysis sample

<table>
<thead>
<tr>
<th>Centres</th>
<th>Study Arm</th>
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<tbody>
<tr>
<td></td>
<td>Controls (N=3297)</td>
</tr>
<tr>
<td></td>
<td>n</td>
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<tr>
<td>Italy - Turin</td>
<td>859</td>
</tr>
<tr>
<td>Spain - Bilbao</td>
<td>212</td>
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<tr>
<td>Germany - Kiel</td>
<td>203</td>
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<tr>
<td>Belgium - Gent</td>
<td>288</td>
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<tr>
<td>Sweden - Stockholm</td>
<td>426</td>
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<tr>
<td>Greece - Thessaloniki</td>
<td>322</td>
</tr>
<tr>
<td>Austria - Wien</td>
<td>433</td>
</tr>
<tr>
<td>Italy - Novara</td>
<td>209</td>
</tr>
<tr>
<td>Italy - Aquila</td>
<td>222</td>
</tr>
</tbody>
</table>
Outcomes measures

1. **Any smoking** = at least one cigarette in last 30 days
2. **Frequent Smoking** = at least 6 times in last 30 days
3. **Daily smoking** = at least 20 times in last 30 days
4. **Any drunkenness** = at least once in last 30 days
5. **Frequent drunkenness** = at least 3 times in last 30 days
6. **Any cannabis** = at least once in last 30 days
7. **Frequent cannabis** = at least 3 times in last 30 days
8. **Any drugs** = at least once of any illicit drug in last 30 days
Some preliminary considerations

- There is a clear *imbalance* (statistically significant for some outcomes) between controls and intervention arms
  - it is limited to 2 centres and the only explanation is chance
- There are very small (and statistically non significant) differences among the *study arms*
  - for power considerations, the following analysis will be done pooling together intervention arms
2. the EU-Dap Study

Adjusted analysis

- Following adjustments are needed:

1. to control for the **cluster effect** (i.e. to correct the **inflated precision** due to the lower **intraclass variability**)

2. to correct for the **imbalance in the baseline characteristics**

3. to control for the **differences in prevalence** among centres
2. the EU-Dap Study

Adjusted analysis

- a **Multilevel regression model** (Random Effect Model) was fitted
  - with 3 levels - center, class, student
  - **baseline variables** to control for imbalance
  - **daily smoking** (as fixed effect) to control for differences in prevalence
## Crude effects

<table>
<thead>
<tr>
<th></th>
<th>CTRLs</th>
<th>INTs</th>
<th>Crude</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>n/N*</td>
<td>n/N*</td>
<td>PR (95%CI)</td>
</tr>
<tr>
<td>Any smoking</td>
<td>642/3059</td>
<td>531/3098</td>
<td>0.82 (0.74-0.91)</td>
</tr>
<tr>
<td>Frequent smoking</td>
<td>407/3059</td>
<td>315/3098</td>
<td>0.76 (0.67-0.88)</td>
</tr>
<tr>
<td>Daily smoking</td>
<td>294/3059</td>
<td>200/3098</td>
<td>0.67 (0.57-0.80)</td>
</tr>
<tr>
<td>Any drunkenness</td>
<td>363/3112</td>
<td>265/3145</td>
<td>0.72 (0.62-0.84)</td>
</tr>
<tr>
<td>Frequent drunkenness</td>
<td>123/3112</td>
<td>77/3145</td>
<td>0.62 (0.47-0.82)</td>
</tr>
<tr>
<td>Any cannabis</td>
<td>230/3157</td>
<td>157/3179</td>
<td>0.68 (0.56-0.83)</td>
</tr>
<tr>
<td>Frequent cannabis</td>
<td>141/3157</td>
<td>92/3179</td>
<td>0.65 (0.50-0.84)</td>
</tr>
<tr>
<td>Any drug</td>
<td>294/3171</td>
<td>224/3191</td>
<td>0.76 (0.64-0.89)</td>
</tr>
</tbody>
</table>
## Adjusted effects

<table>
<thead>
<tr>
<th></th>
<th>Multilevel</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>POR (95%CI)</td>
<td>ARR</td>
<td>NNT</td>
</tr>
<tr>
<td>Any smoking</td>
<td>0.88 (0.71-1.08)</td>
<td>2.5%</td>
<td>40 (188-22)</td>
</tr>
<tr>
<td>Frequent smoking</td>
<td>0.86 (0.67-1.10)</td>
<td>1.9%</td>
<td>54 (459-29)</td>
</tr>
<tr>
<td>Daily smoking</td>
<td>0.70 (0.52-0.94)</td>
<td>2.9%</td>
<td>35 (66-24)</td>
</tr>
<tr>
<td>Any drunkenness</td>
<td>0.72 (0.58-0.90)</td>
<td>3.3%</td>
<td>31 (57-21)</td>
</tr>
<tr>
<td>Frequent drunkenness</td>
<td>0.69 (0.48-0.99)</td>
<td>1.2%</td>
<td>82 (305-47)</td>
</tr>
<tr>
<td>Any cannabis</td>
<td>0.77 (0.60-1.00)</td>
<td>1.7%</td>
<td>60 (223-34)</td>
</tr>
<tr>
<td>Frequent cannabis</td>
<td>0.76 (0.53-1.09)</td>
<td>1.1%</td>
<td>93 (989-49)</td>
</tr>
<tr>
<td>Any drug</td>
<td>0.89 (0.69-1.15)</td>
<td>1.0%</td>
<td>98 (-255-41)</td>
</tr>
</tbody>
</table>
## Gender differences

<table>
<thead>
<tr>
<th></th>
<th>Boys</th>
<th>Girl</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>POR (95%CI)</td>
<td>POR (95%CI)</td>
</tr>
<tr>
<td>Any smoking</td>
<td>0.88 (0.66-1.18)</td>
<td>0.86 (0.65-1.15)</td>
</tr>
<tr>
<td>Frequent smoking</td>
<td>0.68 (0.50-0.93)</td>
<td>1.07 (0.74-1.55)</td>
</tr>
<tr>
<td>Daily smoking</td>
<td>0.49 (0.34-0.71)</td>
<td>0.99 (0.64-1.52)</td>
</tr>
<tr>
<td>Any drunkenness</td>
<td>0.64 (0.49-0.85)</td>
<td>0.86 (0.63-1.18)</td>
</tr>
<tr>
<td>Frequent drunkenness</td>
<td>0.68 (0.45-1.04)</td>
<td>0.66 (0.37-1.18)</td>
</tr>
<tr>
<td>Any cannabis</td>
<td>0.62 (0.45-0.85)</td>
<td>1.05 (0.70-1.58)</td>
</tr>
<tr>
<td>Frequent cannabis</td>
<td>0.60 (0.40-0.91)</td>
<td>1.17 (0.59-2.33)</td>
</tr>
<tr>
<td>Any drug</td>
<td>0.64 (0.48-0.86)</td>
<td>1.40 (0.95-2.04)</td>
</tr>
</tbody>
</table>
2. the EU-Dap Study

Discussion (i)

- **Unplugged** appears to work, with PORs from 0.80 to 0.70, across all conditions under study.

- Weaknesses:
  - short term effects
    - in any case a delay
    - the large majority of studies showing initial positive effects tended to maintain long-term reductions (Skara 2000)
  - imbalance among controls and intervention
    - a presumable effect of chance
    - controlled by inclusion of baseline level of the variable

- strengths
  - large sample size
  - context heterogeneity
Discussion (ii)

• Major issues to discuss
  – lack of effect of the added components (parents and peers involvement)
  – lack of effect for girls
  – Specific effect of *Unplugged* or general effect of *Comprehensive social influence approaches*?
Conclusions

- Unplugged is the first program with evidence of effectiveness in European context for multiple substances of abuse

- **Eu-Dap 2** is recently started:
  - to continue the follow-up
  - to review the Intervention Manual according to performance analysis
  - to prepare a *Dissemination Guidance*, for policy makers and school authorities on the way to diffuse the programme
  - to test in the field the effectiveness of *Guidance*
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