EU-Dap Final Conference
Lisbon 15-17 December 2005

RATIONALE AND STUDY DESIGN

Roberta Siliquini

OED Regione Piemonte
in almost all schools in Europe an intervention against drugs is carries out each year... but

... they are never evaluated
in almost all schools in Europe an intervention against drugs is carried out each year... but

... they are never evaluated

1. Is not acceptable that an intervention carried out on healthy population could cause harm

2. No information is given about risk factors and natural history
CONTRIBUTE TO THE PRODUCTION OF EVIDENCE CONCERNING THE EFFECTIVENESS OF DRUG PREVENTION PROGRAMME
- a complex intervention
- aimed either to curb initiation with drugs
- or to delay transition from experimental to addiction
- of tobacco, alcohol, cannabis and other drugs

CONTRIBUTE TO THE PRODUCTION OF EVIDENCE CONCERNING THE EFFECTIVENESS OF DRUG PREVENTION PROGRAMME
A rigorous evaluation...

- A control group
- A random assignment of subjects
- A standardized intervention
- A standardized evaluation tool
- A continuos monitoring process

Control
- Basic intervention
- Basic intervention + peer
- Basic intervention + parents
A rigorous evaluation...

- A control group
- A random assignment of schools
- A standardized intervention
- A standardized evaluation tool
- A continuous monitoring process

CLUSTER RANDOMIZED STUDY

Control
Basic intervention
Basic intervention + peer
Basic intervention + parents
Study base and study population

- 12-14 years old adolescents
  - age of students must be under the modal age of prevalence
  - the prevalence at the first year of follow up
  - the probability to stay 2 years or more in the same school
Study base and study population

- 12-14 years old adolescents
  - age of students must be under the modal age of prevalence
  - the prevalence at the first year of follow up
  - the probability to stay 2 years or more in the same school

- Inclusion of schools criteria
  - have at least two classes
  - to be a 'normal school'
  - willingness to be included in the study with at least 2 classes
  - not strong prevention packages already carried out
Sample size

INTERCLASS CORRELATION COEFFICIENT \( \rho \)

From others study ICC = 0.06-0.015

INFLATION FACTOR = 1+(m-1) \( \rho \)
Sample size

- Commonly employed values for statistical test
  \[ \alpha = 0.05 \quad \text{power}=0.80 \]

- Intervention effect corresponding to RR= 1.5

- Class size = 20
Sample size

- Commonly employed values for statistical test
  \( \alpha = 0.05 \quad \text{power}=0.80 \)

- Intervention effect corresponding to RR= 1.5

- Class size = 20

15 schools for each center (30 for Torino and Stockholm)
  a ratio of 3 (intervention): 2 (controls)
  6600 students
Random assignment

- List of the area school meeting base population criteria
- Exclusion of schools not meeting criteria
- Stratification in 3 strata according to social class
- Extraction (by chance) of the schools in each strata
- Contact of headmaster and agreement
- Random allocation to study arms
### NUMBER OF SCHOOLS RANDOMISED AND DROPPING OUT AFTER RANDOMISATION, BY STUDY ARM AND CENTER

<table>
<thead>
<tr>
<th>Centres</th>
<th>Study arm</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Basic</td>
<td>Parent</td>
</tr>
<tr>
<td>Italy/Torino</td>
<td>6 1</td>
<td>6 0</td>
</tr>
<tr>
<td>Spain/Bilbao</td>
<td>3 2</td>
<td>3 2</td>
</tr>
<tr>
<td>Germany/Kiel</td>
<td>3 0</td>
<td>3 0</td>
</tr>
<tr>
<td>Belgium/Gent</td>
<td>5 3</td>
<td>5 3</td>
</tr>
<tr>
<td>Sweden/Stockholm</td>
<td>6 1</td>
<td>6 1</td>
</tr>
<tr>
<td>Greece/Thessaloniki</td>
<td>3 0</td>
<td>4 0</td>
</tr>
<tr>
<td>Austria/Vienna</td>
<td>3 0</td>
<td>3 2</td>
</tr>
<tr>
<td>Italy/Novara</td>
<td>3 2</td>
<td>2 0</td>
</tr>
<tr>
<td>Italy/L’Aquila</td>
<td>3 0</td>
<td>3 0</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>35 9 (25.7%)</strong></td>
<td><strong>35 8 (22.9%)</strong></td>
</tr>
</tbody>
</table>
Evaluation tool

- Pre-post questionnaire
  - Self completed (October-December 2004-2005)
  - Self completed at the end of the scholar year
  - Foreseen a follow up at 2-3-5 years
  - Most of the questions come from EDDRA bank
  - About 1 hour for filling it
Evaluation tool

- Pre-post questionnaire

Social environment
Own substance use
Knowledge and opinion about substances
Substances use in the nearest environment
Family and social environment
School environment and climate
Problems and skills
Evaluation tool

\* Pre-post questionnaire

- Self completed (October-December 2004-2005)
- Self completed at the end of the scholar year
- Foreseen a follow up at 2-3-5 years

- Most of the questions come from EDDRA bank
- About 1 hour for filling it

- Anomymous but allowing the linkage between pre and post test
SELF-GENERATION SHEET FOR THE ANONYMOUS CODE

Name

Surname

Birth date (dd/mm/yyyy)

Mother’s name

Father’s name

Paternal Grandmother’s name

Your eyes colour

Green
Brown
Black
Blue
Grey
QUESTIONNAIRE
on attitudes, use, facts
on non-nutritional substances
Questionnaire evaluation

* Pilot study

- September 2004, coordinated by Stockholm center
- Participants: Greece, Italy (Torino, Novara), Spain, Sweden

- Objectives:
  - test the application of the link algorithm
  - test-retest reliability of the algorithm
  - Test of the anonymous link procedures
  - Test-retest reliability of the questionnaire form
  - General acceptance of the questions
  - Test of cost-efficiency of imput options
### Questionnaire evaluation

**EUDAP pilot study: participants by centre**

<table>
<thead>
<tr>
<th>CENTRE</th>
<th>Anonymous code generation (AC)</th>
<th>Anonymous code link¹ (AL)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>CLASSES</td>
<td>STUDENTS</td>
</tr>
<tr>
<td></td>
<td>N.</td>
<td>N.</td>
</tr>
<tr>
<td>Italy 1/Turin</td>
<td>3</td>
<td>63</td>
</tr>
<tr>
<td>Italy 2/Novara</td>
<td>4</td>
<td>85</td>
</tr>
<tr>
<td>Spain/Portugalete</td>
<td>2</td>
<td>28</td>
</tr>
<tr>
<td>Sweden/Stockholm</td>
<td>2</td>
<td>46</td>
</tr>
<tr>
<td><strong>All centres</strong></td>
<td><strong>11</strong></td>
<td><strong>222</strong></td>
</tr>
</tbody>
</table>
### Questionnaire evaluation

**EUDAP pilot study: proportion of successfully linked anonymous code by number of digit**

<table>
<thead>
<tr>
<th>Centre</th>
<th>Digits included in the link procedure</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>All 9 digits</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>Italy 1</td>
<td></td>
</tr>
<tr>
<td>Italy 2</td>
<td></td>
</tr>
<tr>
<td>Spain</td>
<td></td>
</tr>
<tr>
<td>Sweden</td>
<td></td>
</tr>
<tr>
<td>All centres</td>
<td></td>
</tr>
</tbody>
</table>
Process monitoring
- Process Monitoring - DE V2.2 -

"Unplugged" Base Program

"Unplugged" P2P Program

Teachers' Training

Questionnaire Survey

ANNEX1 ANNEX2

Parents' Meeting Program

Control Classes Programs

Teachers' Training Ass.

Drop-out of Trial Units

ANNEX3 ANNEX4

ANNEX5 ANNEX6

ANNEX7 ANNEX8

EpiData 3.0

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Elaborazione e organizzazione

G.Luca Cuomo

OED 2004. Piemonte/Italy

AutoPlayer ottimizzato per VGA 800x600

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