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STUDY PROTOCOL

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Protocol for evaluation of program effectiveness

1. The importance of the effectiveness evaluation

Most prevention of substance use in the school environment is based on behavioural theory (Tobler 2000), and aims at reducing the onset of adolescents' alcohol, tobacco and drug use by decreasing personal and social risk factors and by strengthening personal and social protective factors (Ennett 2003).

Several studies have compared the effectiveness of different school-based interventions. Life Skills (Botvin 1995), Project Northland (Perry 1996), The Midwestern Prevention Project (Pentz 1989), Project SMART (Hansen 1991) and Project ALERT (Ellickson 1993) are examples of school-based prevention programs teaching adolescents resistance-general- social, and personal skills. Although the prevention program with a higher impact in the reduction of drug initiation appears to be the Life Skills model (Faggiano 2005), results from most projects generally show a small effect on tobacco use, and inconsistent effects on alcohol and drug use (Stothard 2000, Tobler 2000).

These programs have been mostly developed in North America, a fact which may imply differences in effectiveness, when implemented in other cultural contexts. A paper from U.K. (Ashton 2003) underlines both methodological and dissemination problems in the implementation of complex interventions such as Life Skills e.g. in the European setting.
Outside of the US/Australian context, the evaluation of the effectiveness of programs is very rare, and when performed it is frequently conducted with flawed methods (non-random allocation, lack of a control group, lack of adequate statistical analysis) (Faggiano 2005).

Since there is some suspicious that prevention intervention can make harm (Dukes 1997; Hawthorne 1996), the implementation of a program should be made only when the program was rigorously evaluated. From the ethical point of view, in fact, it is absolutely not acceptable that an intervention, carried out without an expressed need, could cause harm (Gillon 1994).

The EU-Dap Unplugged project (www.eudap.net), held in Europe from 2003 to 2009, was fund by the European Commission to develop and test an European Comprehensive Social influence program for preventing tobacco, alcohol and drugs use among adolescent. In the multicentric European project, the evaluation showed that the program was effective at short term in preventing daily cigarettes use, drunkenness episodes and cannabis use (Faggiano 2008), and that the effects on drunkenness episodes and cannabis use were maintained at 15 months follow-up (Faggiano 2010).

The UNODC ROMENA/Mentor Arabia project aspires to evaluate the effectiveness of the Unplugged program, when adapted and implemented in countries of Middle East and North Africa.

2. Objectives of the study

One of the aims of the UNODC ROMENA/Mentor Arabia project is to evaluate the effectiveness of a drug prevention program developed for European context when adapted and implemented in countries of Middle East and North Africa.

The evaluation of effectiveness of Unplugged in Egypt, Jordan, Lebanon, Morocco, Kuwait and United Arab Emirates will be performed through a *cluster randomized controlled trial* with two experimental groups. Following this study design, the schools will be randomly assigned to the following groups:

- Unplugged (+ parents involvement)
- Usual Curriculum

3. Identification of area, schools, grade

The countries participating in the evaluation of effectiveness of Unplugged must choose the area of the program implementation and evaluation at the beginning of the study.

The **area** can be the whole country, a region, a district, according to the country possibilities and the number of schools in the target grade.

The schools to approach and invite to participate to the RCT must be chosen according to the following **inclusion criteria**:

- to have at least **2 classes** in the grade under study;
- to be a **"normal"** school: special profiles, such as institutes for mentally retarded people, confessional or foreign languages schools are excluded;
- **not** to be involved in other similar prevention interventions targeted to the grade of interest.

In case of involvement of both private and public schools, it is strongly suggested to involve an equal number of private and public schools. An entire sample of public schools is possible, whilst an entire sample of private schools won't be accepted.

Since the program is effective among 11/12-14 years old pupils, the target grade can be 11, 12, 13 or 14 years old; however, it is strongly suggested to choose the earliest possible grade. This choice must be done taking into consideration the possibility to survey the pupils at 1 year follow-up, together with the natural history of smoking and other drugs behaviour: the age of students must be under the modal age of prevalence.

Taking into account these criteria, the age of pupils involved in the study is:

- 11-14 years old for Egypt
- 13-14 years old for Jordan
- 12-13 years old for Lebanon
- 13-14 years old for Morocco
- 12-13 years old for Kuwait
- 12-13 years old for United Arab Emirates

The project teams of the participating countries will have to approach and invite a certain number of schools in order to reach the sample size needed to perform the evaluation (table 1). It is likely that not all the schools approached will accept to participate in the evaluation study. It is therefore suggested to **enlarge the sample of schools to approach**, in order to achieve the minimum number of schools needed for the evaluation.

4. Invitation of schools to participate in the randomized controlled trial

The schools **accepting to participate in the evaluation study** will be included in a **specific excel file provided by OED staff**. Some information will be recorded in the file, in order for OED to check the eligibility criteria and to classify the schools in 3 social class groups (high, medium, low). The social classification will be done by OED staff using the information provided by the centers. This information will be used to balance the social class strata during the randomization process. The database containing all these information will be sent to OED staff for the random allocation in June 2010 at the latest.

The approached schools have to be informed from the beginning that the participation to the evaluation will imply that the school can be allocated to the intervention arm or to the control group, and that **they will known the result of the allocation only afterwards**.

The main difference among the interventions and the control groups is that the **intervention arm** ("Unplugged + parents involvement") will implement the program in the school year 2010/2011, whilst the **control** arm ("Usual Curriculum") will be able to implement the program in the target grade in the year following the experimental evaluation (2011/2012). All the Usual Curriculum schools will be given the possibility to be trained in specific Unplugged training courses held in summer/autumn 2011.

It is important to clarify to the **control schools** ("Usual curriculum") that they will be able to implement the program the year after but only in classes ***different*** from those who received the questionnaire. It is in fact important that the control pupils remains controls: it is likely they will be asked again to fill in the questionnaire the year after (at 1 year follow-up), and it is important that they remain free from the intervention to act as control pupils.

All the **intervention and control classes** will administer **a questionnaire** investigating the knowledge, intentions and behaviours regarding tobacco, alcohol and substance use, at baseline (**before the start of Unplugged**) and after the end of the program (**after the end of Unplugged**).

A minimum number of schools participating to the randomized controlled trial has to be reached in each country, according to sample size calculations. The minimum number of schools to be randomized in each country is described in Table 1. A larger number is obviously possible and even welcome.
From the estimated sample, the total number of pupils who will receive Unplugged in this phase is **3820**, and is calculated considering **4 classes per each school**, and **25/30 pupils per class**. However, the total number of pupils surveyed is **7960** (**4140** are controls and will receive only the questionnaire). These numbers will change a little due to the actual number of schools and classes accepting to participate and the actual number of pupils in the classes.

Table 1. Study sample (estimating 4 classes per school and 25 pupils per class)

	Egypt	Jordan	Kuwait	Lebanon	Morocco	United Arab Emirates	total
Minimum number of schools participating in the randomized controlled evaluation study	**8**	**15**	**12**	**15**	**10**	**15**	**75**
Pupils per class	30	30	25	25	25	25	
Number of schools to be randomized (pupils) Unplugged (+ parents involvement) Usual Curriculum	 4 (480) 4 (480)	 7 (840) 8 (960)	 6 (600) 6 (600)	 7 (700) 8 (800)	 5 (500) 5 (500)	 7 (700) 8 (800)	 36 (3820) 39 (4140)
Number of pupils approximately surveyed (both conditions)	**960**	**1800**	**1200**	**1500**	**1000**	**1500**	**7960**

5. Random allocation

Once obtained the consent of the schools to participate in the randomized controlled trial, and the information needed for the random allocation, the **database** containing the list of the schools has to be sent to the OED team for the random allocation.

The OED Institute will give each school a **unique code**, and will perform the random allocation, balancing the allocation according to the social strata. The OED Institute will also be responsible of the **registration of the trial** in an international database of randomized controlled trials.
The list of the schools accepting to participate in the RCT has to be sent to OED Institute in **Spring/early Summer 2010, as soon as the agreement with the schools will be taken**. The results of the random allocation will be communicated to the centers approximately **two weeks after**.

After the random allocation, the training of teachers in the schools allocated to the intervention groups will be organized and managed by the local project team.

In all the schools, independently from their group of allocation, **3/4 classes** in the target grade will be administered the questionnaire a first time in **October/November 2010** for the pre-test survey and a second time in **May 2011** for the post-test survey, and where possible a third time in **May 2012** for one year follow-up survey.

The 4 classes will be chosen by the local project team in agreement with the school. The list of the chosen classes will be sent to the OED team. Each class will be attributed an **unique code** by the OED team, to be put on the **first page of the questionnaire**. This code, together with the school code, is needed to take into account the school/class level at the analysis stage.

6. Questionnaire

The questionnaire to be administered at the baseline, post-test and follow-up surveys is derived from that used in the EU-Dap study. The **modified questionnaire** contains some new questions on social status of the family, more details on the use of alcohol, and some new validated questions on intermediate variables.

The main sections of the questionnaire are:

- social environment;
- own tobacco, alcohol and substance use;
- knowledge & opinions about substances
- substance use in the nearest environment;
- family and social environment;
- school environment and school climate;
- problems and skills.

With the aim to include already validated questions in the questionnaire, most of the questions have been caught from the EDDRA data bank, but some have been taken from other surveys. The sources of the modified questionnaire are listed here.

Question #	Sources
(1)	EMCDDA
(2)	EMCDDA
(3)	HBSC 1986, 1990,1994, 1998
(4)	EMCDDA
(5,6)	ESPAD 2007
(7-8-9-10)	HBSC FAMILY AFFLUENCE SCALE
(11)	ESPAD 2003
(12)	HBSC 1986 1990 1994 and 1998
(13)	EMCDDA
(14)	ESPAD 2007
(15)	ESPAD 1995
(16, 17)	ESPAD 2007
(18)	EMCDDA
(19, 20)	ESPAD 2003
(21, 22, 23)	EMCDDA
(24)	RATING (Swedish cohort)
(25)	ESPAD 2003
(26, 27)	HBSC 1998
(28)	PROJECT ALERT
(29)	HBSC
(30)	ESPAD 2003
(31)	EMCDDA
(32)	FAMILY SCALE (Braken)
(33, 34)	ESPAD
(35)	RATING (Swedish cohort)
(36)	HBSC 86, 90, 94, 98
(37)	HBSC 94, 98
(38)	ESPAD 2003

(39) EMCDDA
(40) RATING (Swedish cohort)
(41) EMCCDDA + ESPAD 2007
(42) Fit 5-6 Stell dir vor. (Germany)

The questionnaire will be translated and sent by OED staff to the evaluators of the participating countries. After reaching a general agreement on the acceptability of the questions, the questionnaire will be piloted in a class (see below).

In the translation of the questionnaire, special care is needed for **question 20**, where the translation/adaptation team must choose the list of substances to be included in the examples. It is in fact possible to change the list of the drugs according to the local conditions.
On the contrary, it is necessary that **all other questions closely match the standard questionnaire**. In case it is needed to delete questions, an agreement has to be reached with OED staff.

7. Questionnaire's Pilot Study

A small **piloting** of the questionnaire should be performed at least at the level of one of the participating countries, but if possible in all the countries.

The aims of the Pilot Study are:

1. to test the anonymous code completion
2. to test the understandability of the questions
3. to test the general acceptance of the questions

The pilot study of the questionnaire will take place administrating the questionnaire to **a class** of the chosen the target grade. **Together with the questionnaire** to be filled, **a short form** assessing the understandability of the questionnaire will be administered to the pupils. The **problems** encountered by the pupils in filling the questionnaire and the anonymous code will be taken into account to improve the Arabic version of the questionnaire.

Instructions for the pilot study will be provided together with the short questionnaire. Results, problems encountered by the pupils and solutions adopted will be shared with OED staff and, if needed, a **final version of the questionnaire** will be elaborated by June 2010 at the latest. From this version, the centers will print the copies for the randomized evaluation study.

The questionnaire can be simple or colorful, according to the possibilities of the center.

It will be needed to provide OED with a complete **back-translation of the questionnaire** (from Arabic to English). The back-translation will be sent to OED staff, who will check the translation and will give suggestions when needed. The back-translation should be provided by the end of May 2010 at the latest. From the back-translated version a mask for the data entry will be prepared.

8. Baseline (pre-test) survey

A **pre-test survey** will be undertaken to measure the prevalence of substance use at baseline, and to measure the main confounding factors. It will be also essential to evaluate the effectiveness of the program in preventing the initiation of tobacco, alcohol and drugs use, taking into account the baseline status of the pupils as regards substance use.

The pre-test survey will be administered in **October/November 2010**. The questionnaire will be distributed to the pupils by the center staff and will be self-completed. The same questionnaire will be administered in the subsequent surveys. Before administering the questionnaire to the pupils it is needed to fill the **school** and **class code** (as provided by OED) on the first page. This code is very important to take into account school and class level at the analysis stage.

The administration of the questionnaires will be managed in the classes by **the project manager and his/her assistants**, in agreement with the schools. During the administration of the survey, **the teachers can leave the class**. As regards the presence or absence of the teacher during the surveys, individual agreement will be taken for each class inside the country.
For pupils **absent in the class the very day of the survey**, the teacher will be provided with an empty questionnaire and a pre-paid envelope and will be asked to contact the pupil to obtain the questionnaire filled. The questionnaire will be then sent to the center by the pupil him/herself.

9. Data collection and input of baseline survey

The OED Institute will provide the partners with an **internet mask**, which will be available on the www.eudap.net website. The countries will perform the data entry locally on the internet mask. OED staff will manage the **data management**, performing all the checking needed to provide the final database for the analysis. All these tasks will be performed by Dr. Gian Luca Cuomo.

For a correct data input of the questionnaires, it will be needed to provide a translation of the individual anonymous code near the code filled by the pupil in the first page of the questionnaire. A **"translation book"** will be agreed during the pilot phase (spring 2010). It is important that the codes will be translated from Arabic to Roman characters in the same way for all the surveys. In fact, in case characters will be translated in a different way in the various survey, the second code won't match with the first one and questionnaires will be excluded from the effectiveness analysis.

The **analysis** of the baseline survey will be performed by the OED Institute which will provide the partners with **pooled descriptive statistics** and **specific statistics by country**, approximately 4-6 months after the survey.

10. Process evaluation

For the evaluation of the process, a specific protocol ("**process monitoring protocol**") is provided, including details on the forms to be used and the procedures to follow.

For the process evaluation some tools are provided:

1. a form regarding the activities implemented in the class**,** to be completed by the teacher at the end of each unit, for a total of 12 forms;
2. a form regarding the implementation of other prevention activities (other than Unplugged) in the intervention schools;
3. a form regarding the prevention activities implemented in the control schools;
4. a form on the activities of the parents workshops, to be completed by the Unplugged trainer at the end of each seminar, for a total of 3 forms;
5. a form investigating the overall satisfaction of the teachers with the program;
6. a form investigating the overall satisfaction of the pupils with the program.

The forms should be provided to the teachers during the Unplugged training. The **program manager will keep contacts** with the teachers once a month to monitor the implementation of the Unplugged units and give support. At the end of the program, he/she will collect the process forms (both teachers' and pupils' forms). He/she will also responsible to **enter** the process questionnaires data in a specific mask provided by the OED Institute. The OED Institute will analyse these data and will provide the partners feedback on the implementation of the units and on the possible improvements suggested by the teachers.

11. Follow-up (post-test) survey

The post-test survey will be administered in **May 2011**.

The **same questionnaire** administered in the baseline survey will be used, following the same procedures, according to the protocol.

Again, it will be needed to fill the **school** and **class** code on the first page of the questionnaires before the administration. Following the same procedures adopted for the pre-test survey, the administration of the questionnaires will be managed in the classes by the **project manager** and his/her assistants, and the **teachers** will decide if remain or leave the class.

Again, for pupils **absent in the class the very day of the survey**, the teacher will be provided with an empty questionnaire and a pre-paid envelope and will be asked to contact the pupil to obtain the questionnaire filled. The questionnaire will be then sent to the center by the pupil him/herself.

The self-generated anonymous code will be used to **link pre-test with post-test** questionnaires while protecting the personal identification. This system has the purpose to prevent the linkage between personal identifiers allowing at the same time the linkage between the different questionnaires filled in by the same subject.

12. Data collection and input of post-test survey

As for the baseline survey, the post-test questionnaires will be entered locally in the **internet mask** provided by OED. Afterwards, OED staff will perform all the checking needed to provide the final database to be used for the analysis.

Again, it will be needed to put a translation of the individual anonymous code near the code filled by the pupil in the first page of the questionnaire.

The analysis of the post-test survey will be performed by the OED Institute which will provide the partners with **effectiveness results pooled and by country**, approximately 4-6 months after the post-test survey.

13. 1-year follow-up survey

It is possible that a further survey will be funded and will take place 1 year after the end of the program, in **May 2011**.

In this case, the **same questionnaire** administered in the baseline and post-test survey will be used, following the same procedures, according to the protocol.

As usual, the questionnaires will be entered in the internet mask, the OED Institute will manage the data input, data management, and data analysis, and will provide the partners with **effectiveness results pooled and by country**, approximately 4-6 months after the survey.

14. Publication of data

Results of the surveys will be given to the participating countries **on overall and stratified by center**. The **overall results** will be published in International Journals, and the leaderships of each paper will be agreed in the group. The **results by country** will be published only with the agreement of the single countries and will be of responsibility of the specific country. OED Institute will provide everyone with the data and the help necessary for the publication of results.

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Table 2. Timeline of the evaluation study

step	responsability	timeline
Identification of project coordinator and project manager, Unplugged trainers	centers	February-March 2009
Identification of study area, school grade	centers	April 2009
Training of project managers and trainers	all	April 2009
Final protocol for evaluation and monitoring sent to the coordinating institutions	OED	July 2009
Final questionnaire sent to the coordinating institutions to be translated	OED	July 2009
Questionnaire translated/adapted/back translated	coordinating institutions	March 2010
Final protocol for evaluation and monitoring sent to evaluators and coordinators	OED	March 2010
Identification of schools to approach	centers	March 2010
Excel file with school information to be completed sent to the centers	OED	March 2010
Instructions and forms for piloting the questionnaire sent to the coordinating institutions	OED	Late March 2010
Obtaining acceptance to participate to the RCT	centers	April 2010
Pilot test of questionnaire	all	April/May 2010
Analysis of pilot test data and improvements to arabic version of questionnaire	all/OED	May 2010
Completing and sending excel file with information on the participating schools to OED	centers	May/June 2010
Sending back-translation to OED staff	coordinating institutions	June 2010
Unique code attributed to schools and random allocation to control and intervention groups	OED	June 2010
Registration of the trial in an international database of randomized controlled	OED	May 2010
Identification of 4 classes per each school receiving the program and per each control school for the evaluation study	centers	September 2010
Unique code attributed to classes	OED	September 2010
Printing questionnaires for the evaluation	centers	September 2010
Baseline survey	centers	October/November 2010
Data entry of baseline questionnaires	centers	January/February 2011
Process evaluation monitoring	centers	January-March 2011
Mask for process evaluation by OED Institute	OED	February 2011
Results of data analysis (baseline survey)	OED	June 2011
Post-test survey	centers	May 2011
Analysis of process evaluation questionnaires	OED	June 2011
Data entry of post-test questionnaires	centers	June-July 2011
Report on effectiveness	OED	August 2011
1 year follow-up survey	centers	May 2012
Data entry of 1 year follow-up questionnaires	centers	June-July 2012
Report on effectiveness	OED	November 2012