THE EVALUATION OF UNPLUGGED IN NIGERIA

STUDY PROTOCOL

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Protocol for the evaluation of program effectiveness

1. The importance of the evaluation

Most prevention of tobacco, alcohol and substance use in the school environment is based on behavioural theory (Tobler 2000), and aims to reduce 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).

In the last 20 years, several studies evaluated the effectiveness of school-based prevention programs teaching adolescents resistance-, general- social. and personal skills such as Life Skills (Botvin 1995), Project Northland (Perry 1996), The Midwestern Prevention Project (Pentz 1989), Project SMART (Hansen 1991), Project ALERT (Ellickson 1993), and more recently Unplugged (Faggiano 2007, Faggiano 2008, Faggiano 2010).

Most programs were developed in North America, and Unplugged was developed and tested in Europe, a fact which may imply differences in effectiveness, when implemented in other cultural contexts. Methodological and dissemination problems can indeed arise when implementing complex interventions in different settings (Ashton 2003).

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).

2. Objectives of the study

This project aims to evaluate the effectiveness of the Unplugged program when adapted and implemented in Nigeria.

The evaluation is possible thanks to a collaboration between the Nigeria Office of UNODC, the Federal Ministry of Education, the National Drug Law Enforcement Agency and the National Agency for Food and Drug Administration. In this framework, a large scale project was funded by the European Union (project FED/2012/306-744) to promote healthy lifestyles in schools, families and communities in Nigeria. Unplugged was chosen as intervention to be implemented and evaluated in the school setting.

3. Study design

The evaluation of effectiveness of Unplugged in Nigeria will be performed through a *cluster* randomized controlled trial with two arms. Following this study design, the schools will be randomly assigned to the following groups:

- Unplugged
- Usual Curriculum



4. Identification and randomization of schools

The evaluation will be conducted on the entire territory of Nigeria (7 Zones).



In order to make possible the random allocation of schools, the Federal Ministry of Education provided a list of 65 federal schools based in the 7 Zones of the country, available to participate in the study. Five schools participated in the pilot study, so they were excluded from the experimental study.

Sample size calculations were performed. Assuming alpha 0.05 (two-sided), power 0.80, prevalence in the control arm 14.6% and in the intervention arm 10.2%, 45 pupils per class, ICC 0.025, the estimated sample size needed is 1943 per group (overall 3886), corresponding to 14 schools in the intervention and 14 schools in the control arm. This was enlarged to 16 schools in the intervention and 16 in the control arm, to overcome possible drop-outs from the study.

The randomization took place by zone. Number of schools to be randomized to intervention and control arms in each zone was decided based on the size of the population: 4 schools in North Central zone, 2 in Abuja Federal Territory, 4 in North East zone, 6 in North West zone, 4 in South East zone, 4 in South South zone, 8 in South West zone (Table 1).



OED Institute performed the random allocation of schools by zone (Table 2), and assigned to each school a unique code. Within each randomized school, unique codes were provided to the 3 classes to be surveyed.

Table 1. Sample size by zone

Zone	State	Population	population by zone	proportion of population by zone	number fo schools available by zone	number of schools to be randomized by zone	final sample by zone
NC	Benue State	4219244					
NC	Niger State	3950249					
NC	Kogi State	3278487					
NC	Plateau State	3178712					4
NC	Kwara State	2371089					
NC	Nasarawa State	1863275	18861056	12,4	12	4,0	
NE	Bauchi State	4676465					
NE	Borno State	4151193					
NE	Adamawa State	3168101					_
NE	Gombe State	2353879					4
NE	Yobe State	2321591					
NE	Taraba State	2300736	18971965	12,5	8	4,0	
NW	Kano State	9383682					
NW	Kaduna State	6066562					
NW	Katsina State	5792578					
NW	Jigawa State	4348649					6
NW	Sokoto State	3696999					
NW	Zamfara State	3259846					
NW	Kebbi State	3238628	35786944	23,5	10	7,5	
SE	Anambra State	4182032					
SE	Imo State	3934899					
SE	Enugu State	3257298					4
SE	Abia State	2833999					
SE	Ebonyi State	2173501	16381729	10,8	6	3,4	
SS	Rivers State	5185400			-	-,	
SS	Delta State	4098391					
SS	Akwa Ibom State	3920208					
SS	Edo State	3218332					4
SS	Cross River State	2888966					
SS	Bayelsa State	1703358	21014655	13,8	10	4,4	
SW	Lagos State	21013534		,-		.,.	2
SW	Oyo State	5591589					
SW	Ogun State	3728098					
sw	Ondo State	3441024					6
sw	Osun State	3423535					
SW	Ekiti State	2384212	39581992	26,0	11	8,3	
NC	Abuja Federal Capital Territory	1405201	1405201	0,9	3	0,3	2
	overall	152003542	152003542	100	60	32	32
	1	132003342	102000042	100	00	JZ	J2



Table 2. Random allocation of schools to intervention and control arms

RANDOMIZATION TO INTERVENTION AND CONTROL ARMS										
Zone	number of schools	State	City	NAME OF COLLEGE ADDRESS		ALLOCATION	number of classes			
North Central		Benue	Makurdi	FGC, VANDEIKYA	FGC, VANDEIKYA	CONTROL	3			
North Central	4	Kwara	Ilorin	FGC, ILORIN	FGC, ILORIN	INTERVENTION	3			
North Central	4	Nasarawa	Lafia	FSTC DOMA	FSTC DOMA	INTERVENTION	3			
North Central		Niger	Minna	FGC, MINNA	FGC MINNA	CONTROL	3			
North Central	2	FCT	Abuja	FGBC, GARKI	FGBC, APO	CONTROL	3			
North Central	2	FCT	Abuja	FGC, RUBOCHI	PMB 477 GARKI ABUJA	INTERVENTION	3			
North East		Borno	Maiduguri	FGC, MAIDUGURI	PMB 1102	CONTROL	3			
North East	4	Taraba	Jalingo	FSTC, JALINGO		INTERVENTION	3			
North East	4	Gombe	Gombe	FGC, BILLIRI	PMB 007, FGC BILLIRI	CONTROL	3			
North East		Taraba	Jalingo	FGC, WUKARI	PMB 1029	INTERVENTION	3			
North West		Katsina	Katsina	FSTC, DAYI	FSTC DAYI	CONTROL	3			
North West		Kebbi	Birnin Kebbi	FSTC, ZURU	PMB 1022	INTERVENTION	3			
North West	6	Kebbi	Birnin Kebbi	FGC, BIRNIN-YAURI	PMB 1021 YAURI	CONTROL	3			
North West	6	Sokoto	Sokoto	FSC, SOKOTO		INTERVENTION	3			
North West		Zamfara	Gusau	FGC, ANKA	PMB 1001	INTERVENTION	3			
North West		Zamfara	Gusau	FGC DAURA	FGC DAURA	CONTROL	3			
SOUTH EAST		Anambra	Awka	FSTC, AWKA	PMB 6047	INTERVENTION	3			
SOUTH EAST	4	Anambra	Awka	FGC, NISE	PMB 1001 NISE AWKA	CONTROL	3			
SOUTH EAST	4	Ebnoyi	Abakaliki	FGC, OKPOSI	PMB 1, OKPOSE	INTERVENTION	3			
SOUTH EAST		Imo	Owerri	FGC, OKIGWE		CONTROL	3			
South South		Cross River	Calabar	FGC, IKOM	PMB 1035, IKOM	CONTROL	3			
South South	4	Cross River	Calabar	FSC, OGOJA		INTERVENTION	3			
South South	4	Edo	Benin	FSTC, UROMI	FSTC UROMI	INTERVENTION	3			
South South		Rivers	Portharcourt	FSTC, AHOADA	PMB 2243, AHOADA	CONTROL	3			
South West		Ogun	Abeokuta	FGC, ODOGBOLU	P.M.B.2003,ODOGBOL U, OGUN STATE	CONTROL	3			
South West		Ogun	Abeokuta	FSTC, IJEBU-IMUSHIN	PMB 1008 I/IMUSIN	CONTROL	3			
South West		Ondo	Akure	FGC, IDOANI	PMB 1054 IDO-ANI	INTERVENTION	3			
South West		Ondo	Akure	FSTC, IKARE AKOKO	FSTC, IKARE AKOKO	CONTROL	3			
South West		Osun	Oshogbo	FSTC, ILESA	FSTC, PMB 5013, ILESA	INTERVENTION	3			
South West		Оуо	Ibadan	FGC, IKIRUN	FGC, IKIRUN INTERVENTI		3			
South West		Lagos	Ikeja	KING'S COLLEGE	ISLAND, LAGOS	CONTROL	3			
South West		Lagos	Ikeja	FGC, IJANIKIN	FGC, IJANIKIN	INTERVENTION	3			

16 UNPLUGGED 48 CLASSES 16 CONTROL 48 CLASSES

OVERALL 32 schools 96 classes



5. Questionnaire

The questionnaire to be administered at baseline and follow-up survey is derived from that used in the EU-Dap study and subsequent replication trials. A shorter version will be used, that will be piloted and adapted.

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

	(8) (9) (10) (11) (12, 13) (14, 15, 16) (17) (18) (19, 20) (21) (22) (23) (24) (25, 26) (27) (28) (29) (30) (31) (32)	RATING (Swedish cohort) ESPAD 2003 HBSC 1998 PROJECT ALERT HBSC ESPAD 2003 EMCDDA ESPAD RATING (Swedish cohort) HBSC 86, 90, 94, 98 HBSC 94, 98 ESPAD 2003 EMCDDA RATING (Swedish cohort)
1341 FIL 350 STEILUIL VOL. LGEHHAHV)	(33) (34)	EMCCDDA + ESPAD 2007 Fit 5-6 Stell dir vor. (Germany)



6. Questionnaire's Pilot Study

A small piloting of the questionnaire was organized in Spring 2015, in 5 pilot schools: Kwali-Abuja, Kaduna, Enugu, Ikot Ekpene, Yaba-Lagos.

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 took place administrating the questionnaire to one class in each of the 5 pilot schools identified. Together with the questionnaire to be filled, a short form assessing the understandability of the questionnaire was administered to the pupils. The problems encountered by the pupils in filling the questionnaire and the anonymous code were taken into account to improve the local version of the questionnaire.

Questionnaires piloted were sent to OED Institute. From the analysis of the completion of the questionnaires, of the comments received from UNODC staff and of comments received by the pupils, a final version of the questionnaire was agreed.

7. Baseline (pre-test) survey: November 2015

A pre-test survey will be carried out to measure the prevalence of substance use and the main confounding factors at baseline, and to assess the success of the randomization. It will be also useful to evaluate the effectiveness of the program in preventing and reducing the initiation of tobacco, alcohol and drugs use, taking into account the baseline status of the pupils as regards the use of the specific substance.

Instructions for the preparations of materials needed for the surveys and for the administration of the questionnaires will be sent by OED Institute to UNODC Office in early October (Annex 1).

The pre-test survey will be administered in November/early December 2015, in 3 classes per each schools participating in the evaluation. The questionnaire will be administered by the Focal Points and will be self-completed by the students.

Before administering the questionnaires to pupils in the classes, the Focal Points will paste the identification label of the class on the second page of each questionnaire, as indicated in the Instruction sheet (Annex 1).

Specific appointments for the administration of the survey will be taken with each school and class, some days before the survey. The administration of the questionnaires will be managed in the class by the Focal Points.

After collecting the questionnaires, the Focal Point will send the questionnaires to UNODC Office, which in turn will send them to OED Institute.

OED Institute will manage the data input, and the data management, performing all the checking needed to provide the final database for the analysis.



8. Process evaluation

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

The following tools will be provided:

- 1. 12 monitoring forms of the Unplugged units;
- 2. the teacher's satisfaction questionnaire;
- 3. the student's satisfaction questionnaire.

The forms will be sent by OED Institute to UNODC before the training session of Unplugged teachers. The forms will be provided to the teachers during the training sessions.

After completing the forms and collecting the satisfaction questionnaires from the pupils, the teachers will give the forms to the Focal Point who will send them to UNODC Office, that in turn will send them to OED Institute.

9. Follow-up (post-test) survey: May 2016

The post-test survey will be administered in May 2016.

The same questionnaire administered in the baseline survey will be used, following the same procedures, according to the Instructions (Annex 1).

Again, it will be needed to paste the identification label of the class on the second page of each questionnaire. Following the same procedures adopted for the pre-test survey, the administration of the questionnaires will be managed in the classes by the Focal Points.

As for the baseline survey, OED Institute will manage the data input, and the data management, performing all the checking needed to provide the final database to be used for the analysis.

10. Data analysis and reporting

After each survey, as soon as the database for the analysis will be ready, OED Institute will analyse the data and will send a report to UNODC Office.

A scientific paper will be written in order to publish the results of the baseline survey.

A second paper will be prepared to publish results of the effectiveness analysis, in agreement with UNODC Nigeria Office.

The analysis of effectiveness will be carried out according to the appropriate statistical models, as used in previous Unplugged trials. The self-generated anonymous code will be used to link pre-test with post-test questionnaires.



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Evaluation of Unplugged effectiveness in Nigeria: Timetable 2015

				2015						
March	April	May June		July	August	September	October	November	December	
teachers' training session	pilot l	pilot Unplugged 5 schools 10 classes			on of the schools y, experimental, ng, questionnaires	sessions: list of	teacher training participants and articipation	teachers' training sessions		
Un	plugged adaptatic	ons	agreement on adaptations		of Unplugged achers and pupils	handbook	44 teachers s and 2000 books	teachers handbooks, workbooks and monitoring forms to teachers during training sessions		
evaluation meeting										
provision of monitoring forms for pre-pilot			monitoring forms collection and sending to OED	data entry of monitoring forms	process monitoring analysis and reporting					
	excel file for school list by zone and state	sending excel file with school list by zone to OED	randomization of schools	checking availability of schools to participate as controls and interventions		replacement of refusing schools				
	evaluation questionnaire adaptations and instructions	piloting evaluation questionnaire in one or two classes	final version of evaluation questionnaire and instructions, defining layout	organization of questionnaire printing printing printing		preparation of questionnaires Q1 and Q2 for administration: boxes with number needed per class, Q1 and Q2, adding school and class codes				
				identification of questionnaire administrators half-day training of questionnaire administrators for questionnaire calenda		for questionnair (Q1) with each calendar defir	organization of appointments for questionnaire administration (Q1) with each school and class calendar definition per each administrator		questionnaire administration Q1	



Evaluation of Unplugged effectiveness in Nigeria: Timetable 2016

						2016					
January	February	March	April	May	June	July	August	September	October	November	December
implementat	ugged units ir d classes	intervention					training sess schools): list	n of teacher sions (control of participants participation	teachers' trai	ning sessions	
	schools in ord achers during										
process monitoring				collection of monitoring for intervention ar school	rms from nd control	sending process monitoring forms to OED					
sending questionnaires Q1 to OED	data entry of 4000 questionnaires Q1			data management of database Q1	data analysis of Q1 survey	reporting Q1 survey					
	organization of appointments for questionnaire administration (Q1) with each school and class calendar definition per each administrator		questionr administra Q2		sending questionnaires Q2 to OED		ry of 4000 maires Q1	data management of database Q2 and matching	data analysis of effectiveness	reporting effectivenes	



Annex 1: Survey Instructions









First of all, thank you for participating to the evaluation study of the Unplugged program in Nigeria.

You are in charge of administering the questionnaire to the pupils of the three involved classes.

The questionnaire will be administered to each of these classes 2 times in the 2015-16 school year:

- the first survey is on November/ December 2015,
- the second survey is on May/ June 2016.

In this instruction manual you will find:

- A description of the material you just received
- The instructions for checking the material and preparing the questionnaires
- Instruction for administration and collection of questionnaires
- Instruction for sending back the questionnaires to UNODC.

Thank you for your cooperation,

Unplugged Coordination Group













1. Checking material and preparing questionnaires

You received 6 white envelopes (two for each participating class, one for first survey and one for second survey). Fig. 1



Figure 1

Each white envelope contains 50 questionnaires and 1 brown envelope. Inside the brown envelope you will find a sheet of preprinted adhesive labels containing the name and the code of the class. Fig. 2



Figure 2



Unplugged Evaluation Study -Instruction sheet, page 2













2. What to do

Each of these three participating classes of your school need to have a unique class code. Fig. 3

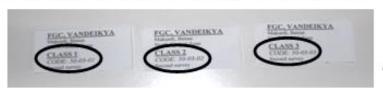


Figure 3

Moreover, each class has two white envelopes: the first labeled "FIRST SURVEY - class name ___ second labeled "SECOND SURVEY - class name _ containing the questionnaires to administer in the first and in the second survey. Fig. 4

Figure

Figure 5



Once you have the list of the 3 participating classes of your school you must decide which one is class 1, class 2 and class 3. To avoid any mistake please write now the class name on the 2 envelopes appertaining to that class (First and Second

For example:

Survey). Fig. 5

FGC, VANDEIKYA North Central Zone CLASS 1 CODE: 50-03-01

FIRST SURVEY CLASS NAME: first-B

Finally, please check that the adhesive label on the white envelope correspond to the label of the brown envelope and to the labels of the sheet included in the brown envelope. Fig. 6 Figure 6





Unplugged Evaluation Study - Instruction sheet, page 3















Did you did it? Put a tick (√) if done:

3. Preparing the questionnaires

Now take from the white envelope the 50 questionnaires.

Take the corresponding label sheet. You must paste the identification label of the class on the second page of each questionnaire. The label must be pasted into the rectangle visible on top of the

second page.

When done insert the 50 questionnaires into the corresponding white envelope.

Repeat the procedure for each of the six white envelope.





Did you did it? Put a tick (✔) if done:





ATTENTION: before administering the questionnaires you should obtain one box to be used to collect the questionnaires in class and to send back to UNODC Office (note that the box must be large enough to contain 150 questionnaires)



Did you did it? Put a tick (√) if done:

You are now ready to administer the questionnaire to the pupils.

Unplugged Evaluation Study – Instruction sheet, page 4













4. Administration of the FIRST questionnaire

The questionnaire filling is expected to last on average 60 minutes but may take longer depending on the context. So it is needed that you agree with class teachers the day and time to dedicate to the questionnaire administration. In that day you will personally administer the questionnaires to the pupils.

At the beginning of the session you will have to introduce the activity to the pupils, explaining that:

- · they are participating to a National survey together with many others Nigerian pupils;
- the survey will take place two times in the year;
- · each time they will have to fill the same questionnaire;
- · the questionnaire is completely anonymous;
- the anonymous code they will fill in the first page is needed to match the first and the second questionnaire in order to see if they changed their mind about something during the year;
- they must remove and destroy themselves the anonymous code page (first page of the auestionnaire):
- it is very important they answer sincerely to each question;
- · after filling it, the pupil must put the questionnaire into the box;
- · gvery question will have only one answer, children should be informed accordingly.

ATTENTION: the anonymous compilation of the questionnaire is crucial for the results of the survey. Neither you nor other people should be able to match the questionnaire to the student who filled it, please be careful to provide this safety.

The questionnaire consists of 2 parts:

1. The anonymous code

Before starting to fill in the question naire the student must complete the anonymous code, that will allow to match the first and the second question naire in a safe a nonymous way.

Some instructions to fill in the code are provided on the first page of questionnaire. Once filled it, the students must copy the code on the second page, then the first page can be removed and destroyed.



ATTENTION: make sure that the students fill in the code by writing capital letters!





Unplugged Evaluation Study —Instruction sheet, page 5









2. The question naire

The questionnaire consists of 3.4 gyestions, some of them could be difficult to answer so you should be ready to help the pupils.

Class teachers should leave the class during the questionnaire administration.

5. Questionnaires collection

You should ask to students to put their filled questionnaires into the provided box to keep them anonymous (or, in case of problem with the box, in any other fashion that will mix up the questionnaires).

At the end of the collection questionnaires from each class, the questionnaires should be placed again in the white envelope with the corresponding class code. The three white envelopes containing the questionnaire should be placed into the box and sent back to UNODC Office as soon as possible (ideally by the end of January).

Second survey

The second survey has to be administered in May or June 2016.

Before administering the question naire you should check the materials: you have to check that all question naires have the corresponding label on the second page.

You should obtain a box for collecting the questionnaires.

You should take agreement with the class teachers about the day and time of the questionnaire administration.

During the filling of the questionnaire you have to help pupils if needed, in particular in filling the anonymous code.

Then, similarly to the first survey, questionnaires from each class should be placed again in the white envelope with the corresponding class code, placed into the box and sent back to UNODC Office as soon as possible (ideally by the end of June).

Thank you for your cooperation, Unplugged Coordination Group

Unplugged Evaluation Study —Instruction sheet, page 6



Annex 2







Dear Unplugged Teacher

First of all, thank you for implementing the Unplugged program in Nigeria!

In order to have information on the difficulties you encountered during the implementation of the program, on your satisfaction with the program and on the satisfaction of the students, it is very important that some monitoring forms will be filled.

In this envelope you will find the monitoring forms to be filled:

- 12 monitoring forms of Unplugged Units (1 form for each unit, 6 sheets) to be filled by you
- 1 Teacher's satisfaction questionnaire to be filled by you
- 50 Student's satisfaction questionnaires—to be filled by your students

Please, fill in each Unit monitoring form immediately after the end of each lesson.

Please, fill in the teacher's satisfaction questionnaire at the end of the program.

Please, dedicate the last 15 minutes of Unit 12 to administer and collect the student's satisfaction questionnaires to pupils in the class.

Finally, please put the monitoring forms, the teacher's satisfaction questionnaire, and all the student's satisfaction questionnaires again in the envelope and deliver it to the Unplugged focal point of the School.

Thank you for your cooperation,

The Unplugged Coordination Group