

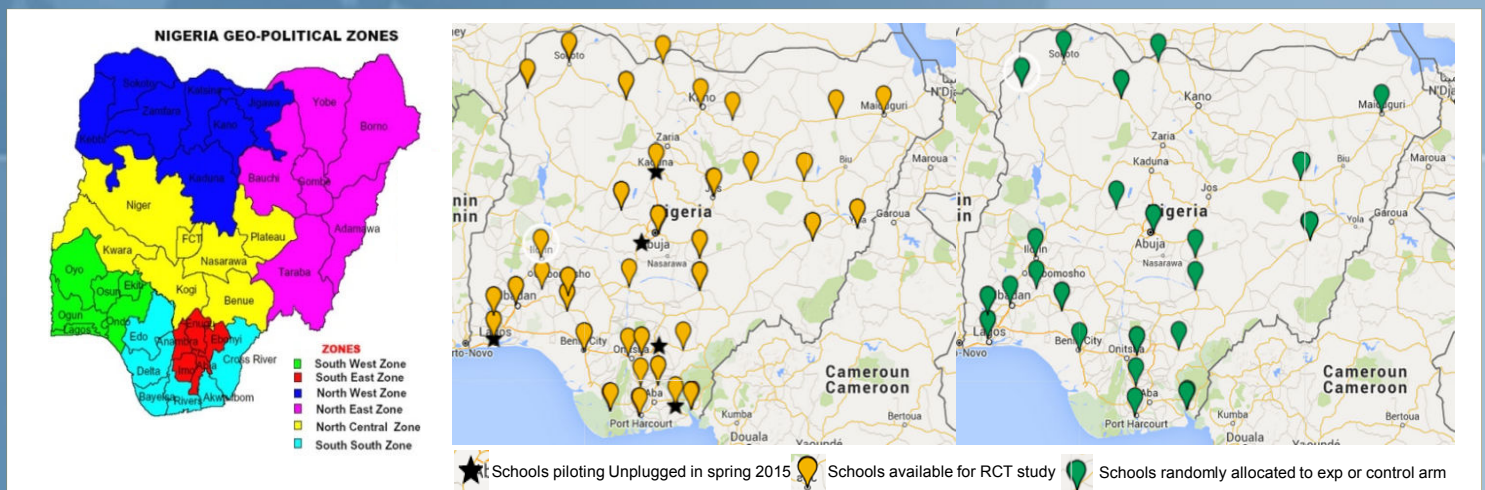


A cluster randomized controlled trial to evaluate the effectiveness of the "Unplugged" program in Nigeria: sample size and study design

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Unplugged is a Social Influence school-based curriculum developed and tested in the European Drug Addiction Prevention trial. It was shown to be effective in reducing cigarette smoking, drunkenness episodes and cannabis use among 12-14 years old adolescents. It has been largely adopted by schools of several countries in the world.



Methods

In the framework of a collaboration among 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, 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. The evaluation will follow a cluster RCT design. 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 is 1943 per group (overall 3886), corresponding to 14 schools in the intervention and 14 in the control arm.

A pilot phase was conducted to pilot the program and the study instruments in 5 schools in Kwali (Abuja), Kaduna, Enugu, Ikot Ekpene, Yaba (Lagos) in Spring 2015.

Results

The Federal Ministry of Education provided a list of 60 federal schools based in the 7 Zones of the country. Thirty-two schools were randomized, 16 to the intervention arm and 16 to the control one. The randomization was performed at the central level, in OED Institute in Torino, and was stratified by zone taking into account the population size. Three classes per school will participate in the study. Pupils will be administered a baseline survey between November and December 2015, and a post-test survey between May and June 2016.

RANDOMIZATION TO INTERVENTION AND CONTROL ARMS				
Zone	State	City	NAME OF COLLEGE	ALLOCATION
North Central	Benue	Makurdi	FGC, VANDEIKYA	CONTROL
	Kwara	Ilorin	FGC, ILORIN	INTERVENTION
	Nasarawa	Lafia	FSTC DOMA	INTERVENTION
North Central	Niger	Minna	FGC, MINNA	CONTROL
	FCT	Abuja	FGBC, GARKI	CONTROL
North East	FCT	Abuja	FGC, RUBOCHI	INTERVENTION
	Borno	Maiduguri	FGC, MAIDUGURI	CONTROL
	Taraba	Jalingo	FSTC JALINGO	INTERVENTION
	Gombe	Gombe	FGC, BILLIRI	CONTROL
North West	Taraba	Jalingo	FGC, WUKARI	INTERVENTION
	Katsina	Katsina	FSTC, DAYI	CONTROL
	Kebbi	Birnin Kebbi	FSTC, ZURU	INTERVENTION
	Kebbi	Birnin Kebbi	FGC, BIRNIN-YAURI	CONTROL
South East	Sokoto	Sokoto	FSC, SOKOTO	INTERVENTION
	Zamfara	Gusau	FGC, ANKA	INTERVENTION
	Zamfara	Gusau	FGC DAURA	CONTROL
	Anambra	Awka	FSTC, AWKA	INTERVENTION
	Anambra	Awka	FGC, NISE	CONTROL
South South	Ebonyi	Abakaliki	FGC, OKPOSI	INTERVENTION
	Imo	Owerri	FGC, OKIGWE	CONTROL
	Cross River	Calabar	FGC, IKOM	CONTROL
	Cross River	Calabar	FSC, OGOJA	INTERVENTION
South West	Edo	Benin	FSTC, UROMI	INTERVENTION
	Rivers	Portharcourt	FSTC, AHODA	CONTROL
	Ogun	Abeokuta	FGC, ODOGBOLU	CONTROL
	Ogun	Abeokuta	FSTC, IJEBU-IMUSHIN	CONTROL
	Ondo	Akure	FGC, IDOANI	INTERVENTION
	Ondo	Akure	FSTC, IKARE AKOKO	CONTROL
South West	Osun	Oshogbo	FSTC, ILESA	INTERVENTION
	Oyo	Ibadan	FGC, IKIRUN	INTERVENTION
	Lagos	Ikeja	KING'S COLLEGE	CONTROL
Lagos	Ikeja	FGC, IJANIKIN	INTERVENTION	

Conclusions

This is the first experimental large scale study organized in Nigeria to evaluate the effectiveness of a school-based prevention program. Many cultural, political, and geographical critical issues in the country can threaten the conduction of the study. However, all the involved Institutions were very enthusiastic about the project and were very collaborative in the pilot phase. We expect these premises will assure good outcomes from the study in 2016.