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.

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 threat 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.