Appendix 1: WHO Trial Registration Data Set (TRDS)

	Data category	**Information**
1.	Primary registry and trial identifying number	Clinical Trial Registry of India (CTRI) Registration number CTRI/2018/09/015706
2.	Date of registration in primary registry	13/09/2018
3.	Secondary identifying numbers	UTN MU/ RG0416001 dated 26/04/2017
4.	Source(s) of monetary or material support	Public Health foundation of India (PHFI) in collaboration with Science and Engineering Research Board (SERB, A Statutory Body under Department of Science and Technology (DST), Government of India)
5.	Primary sponsor	Public Health foundation of India (PHFI) in collaboration with Science and Engineering Research Board (SERB, A Statutory Body under Department of Science and Technology (DST), Government of India)
6.	Secondary sponsor	Manipal Academy of Higher Education, Manipal
7.	Contact for public queries	Principal investigator address & email
8.	Contact for scientific queries	Principal investigator address & email
9.	Public title	Effect of health education on salivary cotinine levels among 12 year olds exposed to second hand tobacco smoke
10.	Scientific title	Effectiveness of a school-based tobacco free intervention on adolescents' knowledge and exposure to Second Hand Tobacco Smoke – A multiphase study
11.	Country of recruitment	India
12.	Health condition(s) or problem(s) studied	Salivary cotinine levels among those exposed to second hand tobacco smoke
13.	Intervention(s)	Health education: The experimental arm will receive the 'tobacco free' intervention, which includes 40 min 'tobacco free' health

		education session delivered once a week for 3 consecutive weeks, using lectures, demonstrations, discussions, storytelling and quiz. Participants will also be given, 'take home brochures' every week that contains messages on the effects of tobacco and how to make their homes smoke-free.
14.	Key inclusion and exclusion criteria	Inclusion criteria: All 12 year old school children in Mangalore, who have consented for the study. Exclusion criteria: Participants who are self-reported smokers
15.	Study type	Interventional parallel study using cluster randomisation method, outcome assessor blinded, to assess if there is any change in the salivary cotinine levels and the knowledge, attitude and behaviour scores of the participants after a 'tobacco free' health educational intervention.
16.	Date of first enrolment	December 2018
17.	Sample size	250
18.	Recruitment status	Recruiting
19.	Primary outcome(s)	• To assess if there is any change in the salivary cotinine levels and the knowledge, attitude and behaviour scores of the participants 12 months after a 'tobacco free' health educational intervention, with reinforcement at 3, 6 and 12 months after intervention.
20.	Secondary outcome(s)	• To develop effective school- based intervention to reduce exposure and improve adolescents' knowledge and attitude towards Second Hand tobacco Smoke and to promote smoke free homes.
21.	Ethics review	Ethical approval has been obtained from The Institutional Ethics Committee (No.17021 dated 13 march 2017). Written informed consent from parents and informed assent from the participants will be obtained by the principal investigator prior to recruitment.
22.	Completion date	June 2021
23.	Summary results	This is a multiphase study with a descriptive cross-sectional questionnaire phase 1 and a phase 2 cluster randomized controlled trial, to determine the effectiveness of a school- based 'tobacco free' health education intervention on adolescents' knowledge and attitude towards Second Hand Smoke. The sample of 250 participants with salivary cotinine levels of > 0.1 ng/mL

		for the second phase will be selected from the Phase 1 study. The experimental arm will receive the 'tobacco free' intervention, which includes 40 min 'tobacco free' health education session delivered once a week for 3 consecutive weeks, using lectures, demonstrations, discussions, storytelling and quiz. Participants will also be given, 'take home brochures' every week that contains messages on the effects of tobacco and how to make their homes smoke-free. The effect of the intervention will be quantitatively assessed by estimating the salivary cotinine levels after the intervention. This research will help in assessing if there is any change in the salivary cotinine levels and the knowledge, attitude and behaviour scores of the participants after a 'tobacco free' health educational intervention.
24.	Individual clinical trial participant level data (IPD) sharing statement	Individual clinical trial participant level data (IPD) will not be shared

Appendix 2: Timeline of the study

	Research Activity	Study period (in months)						
		1-6	7-9	10	11-12	13-14	17-18	23-24
1.	**Phase 1**							
	Eligibility screening	X						
	Parental consent / child assent	X						
	Questionnaire 1 (SHS Questionnaire)	X						
	Questionnaire 2 (Knowledge, attitude Questionnaire)	X						
	Estimation of salivary cotinine		X					
2.	**Phase 2**							
	Allocation			X				
	First Intervention				X			
	Take home brochures				X			
	First follow up –2 month + Questionnaire					X		
	Second follow up – 6 month + Questionnaire						X	
	Third follow up – 12 month+ + Questionnaire + Estimation of salivary cotinine							X