



Clinical Trial Details (PDF Generation Date :- Wed, 10 Aug 2022 16:39:17 GMT)

CTRI Number	CTRI/2018/05/013985 [Registered on: 21/05/2018] - Trial Registered Retrospectively	
Last Modified On	22/06/2020	
Post Graduate Thesis	Yes	
Type of Trial	Interventional	
Type of Study	Screening Dentistry Behavioral Other (Specify) [oral health education]	
Study Design	Randomized, Parallel Group Trial	
Public Title of Study	Effect of Oral health education among 12-15 year old school children in Dharan	
Scientific Title of Study	Effectiveness of oral health education intervention strategies among 12-15-year-old school children in Dharan, Nepal: A randomized controlled trial	
Secondary IDs if Any	Secondary ID	Identifier
	IRC/1086/017	Protocol Number
Details of Principal Investigator or overall Trial Coordinator (multi-center study)	Details of Principal Investigator	
	Name	Dr Krishna Subedi
	Designation	Junior resident
	Affiliation	B.P. Koirala Institute of Health Sciences (BPKIHS)-Dharan, Nepal
	Address	College of Dental Surgery, Department of Public Health Dentistry, BPKIHS-DHARAN, NEPAL 56700 Other
	Phone	977-9842172496
	Fax	
	Email	idebusanhsirk.ks@gmail.com
Details Contact Person (Scientific Query)	Details Contact Person (Scientific Query)	
	Name	Dr Ashish Shrestha
	Designation	Additional Professor
	Affiliation	B.P.KOIRALA INSTITUTE OF HEALTH SCIENCES (BPKIHS)-DHARAN, NEPAL
	Address	College of Dental Surgery, Department of Public Health Dentistry, BPKIHS-DHARAN, NEPAL 56700 Other
	Phone	977-9842155112
	Fax	
	Email	shrestha.ashish@bпкиhs.edu
Details Contact Person (Public Query)	Details Contact Person (Public Query)	
	Name	Dr Krishna Subedi
	Designation	Junior resident
	Affiliation	B.P. Koirala Institute of Health Sciences (BPKIHS)-Dharan, Nepal
	Address	College of Dental Surgery, Department of Public Health Dentistry, BPKIHS-DHARAN, NEPAL



	,and Children involved in similar other studies					
Method of Generating Random Sequence	Computer generated randomization					
Method of Concealment	On-site computer system					
Blinding/Masking	Outcome Assessor Blinded					
Primary Outcome	<table border="1"> <thead> <tr> <th>Outcome</th> <th>Timepoints</th> </tr> </thead> <tbody> <tr> <td>Effectiveness of oral health education will be assessed by calculating mean score of oral hygiene knowledge, attitude and practices, plaque control and gingival health among 12-15-year-old school children in Dharan.</td> <td>3 months and 6 months after baseline data collection</td> </tr> </tbody> </table>	Outcome	Timepoints	Effectiveness of oral health education will be assessed by calculating mean score of oral hygiene knowledge, attitude and practices, plaque control and gingival health among 12-15-year-old school children in Dharan.	3 months and 6 months after baseline data collection	
Outcome	Timepoints					
Effectiveness of oral health education will be assessed by calculating mean score of oral hygiene knowledge, attitude and practices, plaque control and gingival health among 12-15-year-old school children in Dharan.	3 months and 6 months after baseline data collection					
Secondary Outcome	<table border="1"> <thead> <tr> <th>Outcome</th> <th>Timepoints</th> </tr> </thead> <tbody> <tr> <td> i) Effectiveness of active and passive methods of oral health education ii) Effectiveness of oral hygiene knowledge, attitude and practices of 12-15-year-old school children studying in public and private schools of Dharan iii) Impact of an oral health education in terms of plaque control, gingival health and dentition status in 12-15-year-old school children studying in public and private schools of Dharan </td> <td>3 and 6 months after baseline data collection</td> </tr> </tbody> </table>	Outcome	Timepoints	i) Effectiveness of active and passive methods of oral health education ii) Effectiveness of oral hygiene knowledge, attitude and practices of 12-15-year-old school children studying in public and private schools of Dharan iii) Impact of an oral health education in terms of plaque control, gingival health and dentition status in 12-15-year-old school children studying in public and private schools of Dharan	3 and 6 months after baseline data collection	
Outcome	Timepoints					
i) Effectiveness of active and passive methods of oral health education ii) Effectiveness of oral hygiene knowledge, attitude and practices of 12-15-year-old school children studying in public and private schools of Dharan iii) Impact of an oral health education in terms of plaque control, gingival health and dentition status in 12-15-year-old school children studying in public and private schools of Dharan	3 and 6 months after baseline data collection					
Target Sample Size	Total Sample Size=240 Sample Size from India=240 Final Enrollment numbers achieved (Total)=Applicable only for Completed/Terminated trials Final Enrollment numbers achieved (India)=Applicable only for Completed/Terminated trials					
Phase of Trial	N/A					
Date of First Enrollment (India)	No Date Specified					
Date of First Enrollment (Global)	17/01/2018					
Estimated Duration of Trial	Years=1 Months=0 Days=0					
Recruitment Status of Trial (Global)	Open to Recruitment					
Recruitment Status of Trial (India)	Not Applicable					
Publication Details	None yet					
Brief Summary	<small>This study is a randomized, single-blind parallel group measuring the effectiveness of oral health education among 12-15-year-old school children in 240 students studying in 12 government and private school for a period of 6 months in Dharan, Nepal. Oral health education will be reinforced at third and six months to the intervention group. The outcome will be assessed at third and sixth months in both the groups. The primary outcome measure will be mean score of oral hygiene knowledge, attitude and practices, plaque control measured by Tamech-Dharan modified Oral Hygiene Index (OHI) and gingival condition by using OGI and CPTI. Secondary outcome measure will be plaque control measured by Tamech-Dharan modified Oral Hygiene Index (OHI) and gingival condition by using OGI and CPTI.</small>					