



Clinical Trial Details (PDF Generation Date :- Thu, 28 Oct 2021 04:12:21 GMT)

CTRI Number	CTRI/2018/01/011402 [Registered on: 18/01/2018] - Trial Registered Prospectively		
Last Modified On	01/02/2019		
Post Graduate Thesis	No		
Type of Trial	Interventional		
Type of Study	Behavioral		
Study Design	Cluster Randomized Trial		
Public Title of Study	Improving the control of hypertension among school teachers		
Scientific Title of Study	Non-Communicable Disease Risk Factors among Working Population: An Institution Based Study in Kerala, India		
Secondary IDs if Any	Secondary ID	Identifier	
	NIL	NIL	
Details of Principal Investigator or overall Trial Coordinator (multi-center study)	Details of Principal Investigator		
	Name	Dr GK Mini	
	Designation	PRINCIPAL INVESTIGATOR	
	Affiliation	Sree Chitra Tirunal Institute for Medical Sciences and Technology	
	Address	Achutha Menon Centre for Health Science Studies, Sree Chitra Tirunal Institute for Medical Sciences and Technology, Trivandrum, Kerala-695011, India Achutha Menon Centre for Health Science Studies, Sree Chitra Tirunal Institute for Medical Sciences and Technology, Trivandrum, INDIA. Thiruvananthapuram KERALA 695011 India	
	Phone	9495376825	
	Fax		
	Email	gkmini.2014@gmail.com	
	Details Contact Person (Scientific Query)	Details Contact Person (Scientific Query)	
		Name	GK Mini
Designation		PRINCIPAL INVESTIGATOR	
Affiliation		Sree Chitra Tirunal Institute for Medical Sciences and Technology	
Address		Achutha Menon Centre for Health Science Studies, Sree Chitra Tirunal Institute for Medical Sciences and Technology, Trivandrum, Kerala-695011, India Achutha Menon Centre for Health Science Studies, Sree Chitra Tirunal Institute for Medical Sciences and Technology, Trivandrum, Kerala-695011, India Thiruvananthapuram KERALA 695011 India	
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		Name	GK Mini
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	Affiliation	Sree Chitra Tirunal Institute for Medical Sciences and Technology	
	Address	Achutha Menon Centre for Health Science Studies, Sree Chitra Tirunal Institute for Medical Sciences and Technology, Trivandrum,	



	Kerala-695011, India Achutha Menon Centre for Health Science Studies, Sree Chitra Tirunal Institute for Medical Sciences and Technology, Trivandrum, Kerala-695011, India Thiruvananthapuram KERALA 695011 India			
Phone	9495376825			
Fax				
Email	gkmini.2014@gmail.com			
Source of Monetary or Material Support	Source 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))Science and Technology. Government of India			
Primary Sponsor	Primary Sponsor Details			
Name	Sree Chitra Tirunal Institute for Medical Sciences and Technology			
Address	Sree Chitra Tirunal Institute for Medical Sciences and Technology, Medical College.P.O, Trivandrum			
Type of Sponsor	Research institution			
Details of Secondary Sponsor	Name	Address		
	NIL	NIL		
Countries of Recruitment	List of Countries			
	India			
Sites of Study	Name of Principal Investigator	Name of Site	Site Address	Phone/Fax/Email
	Dr GK Mini	Sree ChitraTirunal Institute for Medical Sciences and Technology	Achutha Menon Centre for Health Science Studies, Sree Chitra Tirunal Institute for Medical Sciences and Technology, Trivandrum, Kerala, India-695011. Thiruvananthapuram KERALA	04712524247 gkmini.2014@gmail.com
Details of Ethics Committee	Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
	Institute Ethics Committee, Sree Chitra Tirunal Institute for Medical Sciences and Technology	Approved	07/09/2015	Yes
	Institute Ethics Committee, Sree Chitra Tirunal Institute for Medical Sciences and Technology	Approved	12/12/2018	Yes
Regulatory Clearance Status from DCGI	Status		Date	
	Not Applicable		No Date Specified	
Health Condition / Problems Studied	Health Type		Condition	
	Healthy Human Volunteers		Hypertension	
Intervention /	Type	Name	Details	



Comparator Agent	Comparator Agent	Advice	The controls will be advised to go to their usual health care provider for treatment
	Intervention	Life style intervention	Life style intervention will be delivered for three months at individual and group level to reduce unhealthy diet, including salt consumption, alcohol consumption, encourage physical activity, quitting tobacco and improve hypertension medication adherence. Blood pressure, weight, waist circumference will be monitored regularly.
Inclusion Criteria	Inclusion Criteria		
	Age From	30.00 Year(s)	
	Age To	55.00 Year(s)	
	Gender	Both	
	Details	Eligible participants will comprise consenting male and female teachers of the selected schools, aged 30 years and above. Participants will have a fluent understanding of spoken Malayalam and be willing to participate in the intervention program.	
Exclusion Criteria	Exclusion Criteria		
	Details	No exclusion criteria	
Method of Generating Random Sequence	Computer generated randomization		
Method of Concealment	Other		
Blinding/Masking	Outcome Assessor Blinded		
Primary Outcome	Outcome	Timepoints	
	The primary outcome will be the proportion of hypertensives who achieved adequate control	After three months of intervention	
Secondary Outcome	Outcome	Timepoints	
	proportion of hypertensives who are aware of the condition and proportion of hypertensives who are on treatment Change in risk factors of hypertension such as tobacco, alcohol, physical inactivity and unhealthy diet, and anthropometry (BMI and waist circumference)	three months	
Target Sample Size	Total Sample Size=2200 Sample Size from India=2200 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)	30/01/2018		
Date of First Enrollment (Global)	No Date Specified		
Estimated Duration of Trial	Years=2 Months=0		



Recruitment Status of Trial (Global)	Days=0 Not Applicable
Recruitment Status of Trial (India)	Open to Recruitment
Publication Details	Not Published
Brief Summary	<p>The main objective of the study is to find out the efficacy of lifestyle intervention on the control of hypertension among school teachers aged 30 years and above in Thiruvananthapuram district. Minor objectives are</p> <ol style="list-style-type: none">1. find out the effect of the intervention on awareness of hypertension2. find out the effect of intervention on treatment of hypertension3. find out the effect of intervention on risk factors for hypertension such as tobacco, alcohol, physical inactivity, unhealthy diet and anthropometry (BMI and waist circumference) <p>This study will be conducted among school teachers in Thiruvananthapuram district of Kerala state in India. After the baseline survey, lifestyle interventions will be delivered to school teachers in the intervention group on hypertension and its risk factors. A post-intervention survey will evaluate the change in control of hypertension both in control and intervention group.</p>