



Clinical Trial Details (PDF Generation Date :- Fri, 10 Jul 2020 20:52:32 GMT)

<b>CTRI Number</b>	CTRI/2016/02/006678 [Registered on: 25/02/2016] - <b>Trial Registered Retrospectively</b>	
<b>Last Modified On</b>	24/02/2016	
<b>Post Graduate Thesis</b>	No	
<b>Type of Trial</b>	Interventional	
<b>Type of Study</b>	Behavioral	
<b>Study Design</b>	Other	
<b>Public Title of Study</b>	Improving the control of high blood pressure in rural India	
<b>Scientific Title of Study</b>	Improving the control of hypertension in rural India: Overcoming barriers to diagnosis and effective treatment (CHIRI)	
<b>Secondary IDs if Any</b>	<b>Secondary ID</b>	<b>Identifier</b>
	NIL	NIL
<b>Details of Principal Investigator or overall Trial Coordinator (multi-center study)</b>	<b>Details of Principal Investigator</b>	
	<b>Name</b>	Dr K R Thankappan
	<b>Designation</b>	Professor and Head
	<b>Affiliation</b>	
	<b>Address</b>	Achutha Menon Centre for Health Science Studies Sree Chitra Tirunal Institute for Medical Sciences and Technology, Trivandrum Thiruvananthapuram KERALA 695011 India
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<b>Details Contact Person (Scientific Query)</b>	<b>Details Contact Person (Scientific Query)</b>	
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<b>Details Contact Person (Public Query)</b>	<b>Details Contact Person (Public Query)</b>	
	<b>Name</b>	Dr K R Thankappan
	<b>Designation</b>	Professor and Head
	<b>Affiliation</b>	
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<b>Email</b>	kavumpurathu@yahoo.com

**Source of Monetary or Material Support**

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**Primary Sponsor**

Primary Sponsor Details	
<b>Name</b>	Prof K R Thankappan
<b>Address</b>	Achutha Menon Centre for Health Science Studies Sree Chitra Tirunal Institute for Medical Sciences and Technology Trivandrum, Kerala, India- 695 011 Tel: 91-471-2524400, Fax: 91-471-2446433/2553469 kavumpurathu@yahoo.com
<b>Type of Sponsor</b>	Research institution and hospital

**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 Pallab Maulik	East Godavari, Andhra Pradesh	Dr Pallab K Maulik, the George Institute for Global Health 219-221, Splendor forum, Plot # 3, Jasola district centre, New Delhi - 110025 East Godavari ANDHRA PRADESH	01141588091 01141588090 pmaulik@georgeinstitute.org.in
Dr Nihal Thomas	Rishi valley, Andhra Pradesh	Dr. Nihal Thomas, Professor and Head, department of Endocrinology, diabetes and metabolic syndrome and vice principal (research), Christian medical College, Vellore - 632004. Chittoor ANDHRA PRADESH	04162282694 nihal_thomas@yahoo.com
Prof K R Thankappan	Thiruvananthapuram, Kerala	Prof. K R Thankappan, Head Achutha Menon Centre for Health Science Studies, Sree Chitra Tirunal Institute for Medical Sciences and Technology, Trivandrum -695011 Thiruvananthapuram KERALA	914712524231 914712446433 kavumpurathu@yahoo.com

**Details of Ethics Committee**

Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
Centre for Chronic Disease Control	Approved	14/07/2015	Yes
Institute Ethics Committee, Sree Chitra Tirunal Institute for Medical Sciences and	Approved	23/09/2015	Yes



Technology, Trivandrum			
Office of Research Institutional Review Board, Christian Medical College, Vellore	Approved	11/07/2015	No

**Regulatory Clearance  
Status from DCGI**

Status	Date
Not Applicable	No Date Specified

**Health Condition /  
Problems Studied**

Health Type	Condition
Patients	Hypertension

**Intervention /  
Comparator Agent**

Type	Name	Details
Intervention	Lifestyle interventions through accredited social health activists (ASHAs).	This is lifestyle intervention delivered by ASHA workers for three months at individual and group level to reduce unhealthy diet, including salt consumption, alcohol consumption, encourage physical activity through peer support and improve hypertension medication adherence. Blood pressure, weight and waist circumference monitoring will be done once in two weeks. This is a life style intervention provided by ASHAs for three month. Each participant will be given life style intervention for one hour duration once in every two weeks.
Comparator Agent	Leaflets on hypertension control	Leaflets describing the behavioral intervention for hypertension control and the need for medication adherence will be distributed to all the control hypertensive patients. They will be also advised to go to their usual health care provider for treatment.

**Inclusion Criteria**

Inclusion Criteria	
Age From	18.00 Year(s)
Age To	99.00 Year(s)
Gender	Both
Details	Individuals aged 18 years and above, already aware of hypertension, understanding of the local language, willing to attend a local facility to participate in the program will be included in the study.

**Exclusion Criteria**

Exclusion Criteria	
Details	Individuals aged less than 18 years. Non hypertensives

**Method of Generating  
Random Sequence**

Other
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**Method of  
Concealment**

Not Applicable
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**Blinding/Masking**

Not Applicable
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<b>Primary Outcome</b>	<b>Outcome</b>	<b>Timepoints</b>
	The primary outcome will be the proportion of hypertensives who achieved adequate control	After three months of intervention
<b>Secondary Outcome</b>	<b>Outcome</b>	<b>Timepoints</b>
	<p>Proportion of hypertensives aware of The condition and taking medication</p> <p>Fidelity and process measures of the program will be obtained via meeting reports and attendance records of meetings</p> <p>System outcomes of the program will be obtained via surveys of ASHA and health providers at the end of the intervention.</p>	Three months
<b>Target Sample Size</b>	<p><b>Total Sample Size=1800</b>  <b>Sample Size from India=1800</b>  <b>Final Enrollment numbers achieved (Total)=Applicable only for Completed/Terminated trials</b>  <b>Final Enrollment numbers achieved (India)=Applicable only for Completed/Terminated trials</b></p>	
<b>Phase of Trial</b>	N/A	
<b>Date of First Enrollment (India)</b>	19/11/2015	
<b>Date of First Enrollment (Global)</b>	No Date Specified	
<b>Estimated Duration of Trial</b>	<p><b>Years=1</b>  <b>Months=6</b>  <b>Days=0</b></p>	
<b>Recruitment Status of Trial (Global)</b>	Not Applicable	
<b>Recruitment Status of Trial (India)</b>	Open to Recruitment	
<b>Publication Details</b>	Not Published	
<b>Brief Summary</b>	<p>The main objective of the study is to pilot and evaluate a group based self management education and support intervention program to improve the control of hypertension in three epidemiologically and demographically different locations in rural India at three months compared with the control arm (people with hypertension who do not participate in the group based program).</p> <p>The pilot study will be conducted in three sites, Trivandrum in Kerala and the East Godavari district and Rishy Valley region in Andhra Pradesh. The pilot intervention will be implemented via community based groups to reduce unhealthy diet (including reducing salt and alcohol consumption), encourage physical activity, and improve adherence to anti-hypertensive medication. Blood pressure and weight monitoring will be undertaken every two weeks.</p> <p>This study is a collaborative effort between Monash University, Australia and three participating sites: Sree Chitra Tirunal Institute for Medical Sciences and Technology, Trivandrum, Kerala, George Institute for Global Health India, Hyderabad, Andhra Pradesh and Christian Medical College, Vellore, Tamil Nadu.</p>	