Clinical Trial Details (PDF Generation Date :- Sun, 01 Oct 2023 05:04:48 GMT)

CTRI Number	CTRI/2016/02/006678 [Registered on: 25/02/2016] - **Trial Registered Retrospectively**
Last Modified On	24/02/2016
Post Graduate Thesis	No
Type of Trial	Interventional
Type of Study	Behavioral
Study Design	Other
Public Title of Study	Improving the control of high blood pressure in rural India
Scientific Title of Study	Improving the control of hypertension in rural India: Overcoming barriers to diagnosis and effective treatment (CHIRI)

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 K R Thankappan
Designation	Professor and Head
Affiliation	
Address	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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Details Contact Person (Scientific Query)

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Name	Dr K R Thankappan
Designation	Professor and Head
Affiliation	
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Source of Monetary or Material Support

Source of Monetary or Material Support

Primary Sponsor

Primary Sponsor Details	
Name	Prof K R Thankappan
Address	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
Type of Sponsor	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
Method of Concealment	Not Applicable
Blinding/Masking	Not Applicable

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 aware of The condition and taking medication Fidelity and process measures of the program will be obtained via meeting reports and attendance records of meetings System outcomes of the program will be obtained via surveys of ASHA and health providers at the end of the intervention.	Three months

Target Sample Size	**Total Sample Size=**1800 **Sample Size from India=**1800 **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)	19/11/2015
Date of First Enrollment (Global)	No Date Specified
Estimated Duration of Trial	**Years=**1 **Months=**6 **Days=**0
Recruitment Status of Trial (Global)	Not Applicable
Recruitment Status of Trial (India)	Open to Recruitment
Publication Details	Not Published
Brief Summary	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). 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. 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.