Clinical Trial Details (PDF Generation Date :- Tue, 02 Mar 2021 09:29:47 GMT)

CTRI Number	CTRI/2013/06/003753 [Registered on: 14/06/2013] - **Trial Registered Prospectively**
Last Modified On	07/09/2016
Post Graduate Thesis	Yes
Type of Trial	Interventional
Type of Study	Preventive Screening Process of Care Changes
Study Design	Cluster Randomized Trial
Public Title of Study	A stepped-wedge cluster randomised controlled trial of a primary health care mobile health system for cardiovascular risk management in rural Andrha Pradesh
Scientific Title of Study	SMART Health – India: Systematic Medical Assessment, Referral and Treatment in rural 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	Anushka Patel
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Source of Monetary or Material Support

Source of Monetary or Material Support
> Global Alliance for Chronic Diseases UCL Institute for Global Health 30 Guilford Street London WC1N 1EH United Kingdom

Primary Sponsor

Primary Sponsor Details	
Name	NHMRC GACD
Address	Global Alliance for Chronic Diseases UCL Institute for Global Health 30 Guilford Street London WC1N 1EH United Kingdom
Type of Sponsor	Government funding agency

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 D Praveen	The George Institute for Global Health India	The George Institute for Global Health, INDIA 839C, Road No. 44A Jubilee Hills, Hyderabad - 500033 West Godavari ANDHRA PRADESH	9959777623 dpraveen@georgeinstitute.org.in

Details of Ethics Committee

Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
Centre for Chronic Disease Institutional Ethics Committee, Delhi	Approved	15/04/2013	Yes

Regulatory Clearance Status from DCGI

Status	Date
Not Applicable	No Date Specified

Health Condition / Problems Studied

Health Type	Condition
Patients	CVD

Intervention / Comparator Agent

Type	Name	Details
Intervention	CDSS, Training	The health workers will screen individuals for risk of CVD using the CDSS and will refer the patients to the doctors for confirmation and medication. The health workers will later follow-up each patient on medication at least once every month during the study period (2 years) to encourage adherence to medication and to follow proper lifestyle practices.
Comparator Agent	Normal practice	Compared to normal practice

Inclusion Criteria

Inclusion Criteria	
Age From	40.00 Year(s)
Age To	85.00 Year(s)
Gender	Both

Details	a. Resident of the village selected for the study b. should be able to provide informed consent

Exclusion Criteria

Exclusion Criteria	
Details	a. Individuals below 40 years b. People with intellectual disability that prevents them from comprehending the study principles and requirements

Method of Generating Random Sequence	Stratified randomization
Method of Concealment	Other
Blinding/Masking	Not Applicable

Primary Outcome

Outcome	Timepoints
Difference in proportion of high risk individuals (with or without CVD) who are achieving optimal BP levels (Systolic BP greater than 140 mmHg) between the intervention and control periods	end of 2 years

Secondary Outcome

Outcome	Timepoints
-mean reduction in BP levels -receipt of lifestyle advice by a health care provider -change in other CVD risk factors -self-reported use of BP and other cardiovascular medicines -Quality of life (using the EQ-5D) -CVD events	end of 2 years

Target Sample Size	**Total Sample Size=**16000 **Sample Size from India=**16000 **Final Enrollment numbers achieved (Total)=** **Final Enrollment numbers achieved (India)=**
Phase of Trial	N/A
Date of First Enrollment (India)	01/08/2013
Date of First Enrollment (Global)	No Date Specified
Estimated Duration of Trial	**Years=**2 **Months=**0 **Days=**0
Recruitment Status of Trial (Global)	Not Applicable
Recruitment Status of Trial (India)	Completed
Publication Details	
Brief Summary	The SMARTHealth India study will test whether the SMARTHealth system will assist health professionals and patients in making evidence based management decisions to help prevent heart attack, stroke and related conditions. **Hypothesis:** Compared to usual practice, a primary healthcare worker led clinical decision support system will increase the proportion of high risk individuals achieving optimal BP levels.