



Clinical Trial Details (PDF Generation Date :- Tue, 02 Mar 2021 09:23:11 GMT)

CTRI Number	CTRI/2015/12/006424 [Registered on: 08/12/2015] - Trial Registered Prospectively	
Last Modified On	31/12/2019	
Post Graduate Thesis	No	
Type of Trial	Interventional	
Type of Study	Process of Care Changes Behavioral	
Study Design	Cluster Randomized Trial	
Public Title of Study	A community-based programme for reducing the burden of stroke in rural Gadchiroli, Maharashtra, India	
Scientific Title of Study	The effect of a community-based programme for cardiovascular risk factor control on stroke mortality in rural Gadchiroli, India: A cluster randomised controlled trial	
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 Yogeshwar V Kalkonde MD MSc
	Designation	Team Leader, Rural Chronic Non-communicable Diseases Research Programme and Consultant Neurologist
	Affiliation	Society for Education, Action and Research in Community Health
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	Details Contact Person (Scientific Query)	Details Contact Person (Scientific Query)
Name		Dr Yogeshwar V Kalkonde MD MSc
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Details Contact Person (Public Query)		Details Contact Person (Public Query)
	Name	Dr Abhay T Bang MD MPH
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Source of Monetary or Material Support	Source of Monetary or Material Support			
	> The Wellcome Trust/DBT India Alliance			
Primary Sponsor	Primary Sponsor Details			
	Name	Society for Education Action and Research in Community Health SEARCH		
	Address	Shodhgram, PO and Dist Gadchiroli		
	Type of Sponsor	Other [Non-Governmental Organisation]		
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 Yogeshwar Kalkonde MD MSc	Gadchiroli	SEARCH, Shodhgram Gadchiroli MAHARASHTRA	91-7138-255407 91-7138-255411 yvkalkonde@gmail.com
Details of Ethics Committee	Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
	SEARCH Institutional Ethical Committee	Approved	04/04/2015	No
	SEARCH Institutional Ethical Committee	Approved	31/03/2016	No
	SEARCH Institutional Ethical Committee	Approved	24/03/2017	No
	SEARCH Institutional Ethical Committee	Approved	20/03/2018	No
	SEARCH Institutional Ethical Committee	Approved	13/03/2019	No
Regulatory Clearance Status from DCGI	Status	Date		
	Not Applicable	No Date Specified		
Health Condition / Problems Studied	Health Type	Condition		
	Patients	Cerebral infarction, unspecified		
	Patients	Essential (primary) hypertension		
	Patients	Nontraumatic intracerebral hemorrhage, unspecified		
	Patients	Type 2 diabetes mellitus		
Intervention / Comparator Agent	Type	Name	Details	
	Intervention	Community-based programme for cardiovascular risk factor control	The intervention will include- i) increasing awareness about stroke and its risk factors through yearly community-based awareness campaigns, ii) screening of all individuals 50 years of age and older in the intervention villages for hypertension and diabetes at the beginning of the	



		intervention. This will be done by a community health worker using a electronic blood pressure monitor and checking for glycosuria using urine dipsticks, iii) simplified guideline-based treatment of patients with hypertension (using hydrochlorothiazide, amlodipine and atenolol), diabetes (using metformin and glipizide), and secondary prophylaxis of stroke (using low dose aspirin and a low-dose statin) by an outreach physician, and d) follow up of these patients for medication compliance by the community health worker and counseling of patients to reduce salt, tobacco and alcohol use.
Comparator Agent	Enhanced usual care	Households in this arm will receive information pamphlets describing harmful effects of tobacco at the beginning and at the end of the intervention. The households in this area have access to care for chronic diseases provided by the government healthcare systems and private practitioners.

Inclusion Criteria

Inclusion Criteria	
Age From	50.00 Year(s)
Age To	99.00 Year(s)
Gender	Both
Details	Cluster level: Inclusion criteria: The village 1.should belong to the field practice area of SEARCH in Gadchiroli district 2.should have population >400 Individual level: The individual should - 1.be a resident of the village 2.be 50 years of age or older 3.provide written, informed consent to receive the intervention and with ANY of the conditions listed below to receive treatment and follow up under the intervention 4.with a mean systolic blood pressure of 140 mm Hg or above and mean diastolic blood pressure of 90 mm Hg or above (based on 2 separate readings taken 5 minutes apart) or with a diagnosis of hypertension and on antihypertensive medications, 5.with glycosuria detected using urine dipsticks during screening and random capillary blood glucose of 200 mg/dl or above; or those with outside records showing fasting plasma glucose 126 mg/dL or above or single random plasma blood glucose value of 200 mg/dL or above ; or previous diagnosis of diabetes and taking treatment for diabetes 6.with diagnosis of stroke defined using the World Health Organization's definition as a focal (or at times global) neurological impairment of sudden onset, and lasting > 24 hours (or leading to death), and of presumed vascular origin.

Exclusion Criteria

Exclusion Criteria	
Details	Cluster level:



	1.villages within 5 km distance from Gadchiroli town (district place) Individual level: 1.terminally ill patients 2.patients with cardiovascular or kidney disease that can not be managed in primary care setting														
Method of Generating Random Sequence	Computer generated randomization														
Method of Concealment	Centralized														
Blinding/Masking	Outcome Assessor Blinded														
Primary Outcome	<table border="1"> <thead> <tr> <th>Outcome</th> <th>Timepoints</th> </tr> </thead> <tbody> <tr> <td>Reduction in stroke mortality</td> <td>last 2.5 years of the intervention</td> </tr> </tbody> </table>	Outcome	Timepoints	Reduction in stroke mortality	last 2.5 years of the intervention										
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Target Sample Size	Total Sample Size=5600 Sample Size from India=5600 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)	18/01/2016														
Date of First Enrollment (Global)	No Date Specified														
Estimated Duration of Trial	Years=3 Months=6 Days=0														
Recruitment Status of Trial (Global)	Not Applicable														
Recruitment Status of Trial (India)	Open to Recruitment														
Publication Details	Kalkonde Y, Deshmukh M, Nila S, Jadhao S, Bang A. Effect of a community-based intervention for cardiovascular risk factor control on stroke mortality in rural Gadchiroli, India: study protocol for a cluster randomised controlled trial. <i>Trials</i> . 2019 Dec 23;20(1):764. doi: 10.1186/s13063-019-3870-x.														
Brief Summary	With epidemiological transition, stroke is emerging as an important cause of death and disability in rural India and perpetuates poverty. Community-based interventions that controlled cardiovascular risk factors using well-established medications and lifestyle changes have reduced stroke mortality in developed countries. However, well tested community-based interventions to reduce the stroke mortality in rural areas of India as well as other developing countries are lacking. Stroke mortality in such areas can be potentially reduced in a cost effective manner by using simple guideline-based treatments of cardiovascular risk factors using generic medicines and increasing awareness about stroke. However, delivering such a care in rural areas where there is minimal awareness about stroke and its risk factors, economic resources are limited and healthcare for these problems is not														



easily available is logistically challenging.

This study aims to address these challenges. In this cluster randomized, parallel group, two arm trial we will assess the effect of a healthcare delivery intervention package to control cardiovascular risk factors on stroke mortality. The study will be conducted in an underdeveloped rural area of central India. Thirty two villages will be randomly assigned to the intervention arm and will receive the healthcare delivery intervention while other 32 villages will be assigned to the control arm and will receive enhanced usual care in the form of health education on harmful effects of tobacco at the beginning and at the end of the intervention. The intervention will last for 3.5 years. The intervention will be jointly delivered by a village-based community health worker and a visiting outreach physician. It is a “3 plus 3” intervention in which the outreach physician will provide medical treatment for 3 conditions-hypertension, diabetes and secondary prophylaxis of stroke while the community health worker will provide lifestyle modification counseling to reduce 3 risk factors- salt, tobacco and alcohol use. In the intervention area all the individuals 50 years of age and above will be screened for hypertension, glycosuria and stroke by a village health worker at the beginning of the intervention. These patients will be evaluated by an outreach physician who will confirm the diagnoses and provide guideline-based medical treatment and follow up. The community health workers will follow these patients to promote medication compliance and provide lifestyle modification advice for reducing the risk factors discussed above.