



Clinical Trial Details (PDF Generation Date :- Tue, 19 Oct 2021 15:01:31 GMT)

<b>CTRI Number</b>	CTRI/2015/03/005640 [Registered on: 17/03/2015] - <b>Trial Registered Retrospectively</b>		
<b>Last Modified On</b>	04/08/2021		
<b>Post Graduate Thesis</b>	No		
<b>Type of Trial</b>	Observational		
<b>Type of Study</b>	Cross Sectional Study		
<b>Study Design</b>	Cluster Randomized Trial		
<b>Public Title of Study</b>	Improving access to medicines for rural poor in Tumkur, India		
<b>Scientific Title of Study</b>	Improving equitable access to quality generic medicines for patients with non-communicable diseases in Tumkur, India		
<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>		
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	<b>Designation</b>	Faculty	
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<b>Source of Monetary or Material Support</b>	<b>Source of Monetary or Material Support</b>			
	> Alliance for Health Policy and Systems Research, World Health Organization, Geneva			
<b>Primary Sponsor</b>	<b>Primary Sponsor Details</b>			
	<b>Name</b>	Institute of Public Health		
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	<b>Type of Sponsor</b>	Research institution		
<b>Details of Secondary Sponsor</b>	<b>Name</b>	<b>Address</b>		
	NIL	NIL		
<b>Countries of Recruitment</b>	<b>List of Countries</b>			
	India			
<b>Sites of Study</b>	<b>Name of Principal Investigator</b>	<b>Name of Site</b>	<b>Site Address</b>	<b>Phone/Fax/Email</b>
	Dr Narayana Devadasan	Koratagere	Primary health centres of Koratagere, Department of Health and Family Welfare, Tumkur. Tumkur KARNATAKA	918026421929 deva@iphindia.org
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	Dr Narayana Devadasan	Turuvekere	Primary health centres of Turuvekere, Department of health and family welfare, Tumkur. Tumkur KARNATAKA	918026421929 deva@iphindia.org
<b>Details of Ethics Committee</b>	<b>Name of Committee</b>	<b>Approval Status</b>	<b>Date of Approval</b>	<b>Is Independent Ethics Committee?</b>
	IPH Institutional Ethics Committee	Approved	26/04/2013	Yes
	WHO Ethics Review Committee	Approved	10/05/2013	Yes
<b>Regulatory Clearance Status from DCGI</b>	<b>Status</b>		<b>Date</b>	
	Not Applicable		No Date Specified	
<b>Health Condition / Problems Studied</b>	<b>Health Type</b>		<b>Condition</b>	
	Healthy Human Volunteers		Households with self-reported patients with Diabetes and/or Hypertension	
<b>Intervention / Comparator Agent</b>	<b>Type</b>	<b>Name</b>	<b>Details</b>	
	Intervention	Health services optimisation in PHCs	Intervention PHCs will be offered a package consisting of training and technical support to health staffs (PHC Medical officers, pharmacists and ANMs) to implement continuous care for patients with non-communicable diseases.	



		There will be one such training followed by a refresher training in 10-12 months interval. The overall intervention period is 18 months.
Intervention	Community platforms strengthening	This group will be offered a package of interventions including health services optimisation and material to strengthen existing community participation platforms. The training for ANMs and ASHAs for counselling of NCD patients and ensuring their continuous visit to PHCs for care will happen once followed by a refresher in 10-12 months interval. Organisation of NCD patient group meeting for discussion on improvement of NCD care at PHCs will occur at these PHCs belonging to intervention II arm. The maximum number of time a patient group meeting will occur at a given intervention II PHC is two. Overall intervention period is 18 months.
Comparator Agent	Control	This group of PHCs will receive visits from the study team and observation will be recorded for existing government program for NCD control at these PHCs.

**Inclusion Criteria**

Inclusion Criteria	
Age From	1.00 Year(s)
Age To	99.00 Year(s)
Gender	Both
Details	Any household who self-report a household member with Diabetes and/or Hypertension, who consent to participate in the study after going through the information package provided in local language

**Exclusion Criteria**

Exclusion Criteria	
Details	

**Method of Generating Random Sequence**

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**Method of Concealment**

	Not Applicable
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**Blinding/Masking**

	Not Applicable
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**Primary Outcome**

Outcome	Timepoints
Total health expenditure, out-of-pocket expenditure on medicines by patients with NCDs, proportion of NCD patients registered in PHC, outpatient consultation for NCDs and improved compliance and repeat visits by patients with NCDs	Total health expenditure, out-of-pocket expenditure on medicines by patients with NCDs, proportion of NCD patients registered in PHC, outpatient consultation for NCDs and improved compliance and repeat visits by patients with NCDs

**Secondary Outcome**

Outcome	Timepoints
Average consultation time for NCDs at PHCs,	2013, 2015



	Average duration of stock-outs of medicines at PHC, Proportion of NCD medicines of acceptable (IP) quality at PHC and private pharmacies
<b>Target Sample Size</b>	<b>Total Sample Size=1069</b> <b>Sample Size from India=1069</b> <b>Final Enrollment numbers achieved (Total)=1187</b> <b>Final Enrollment numbers achieved (India)=1187</b>
<b>Phase of Trial</b>	N/A
<b>Date of First Enrollment (India)</b>	03/03/2014
<b>Date of First Enrollment (Global)</b>	No Date Specified
<b>Estimated Duration of Trial</b>	<b>Years=1</b> <b>Months=6</b> <b>Days=0</b>
<b>Recruitment Status of Trial (Global)</b>	Not Applicable
<b>Recruitment Status of Trial (India)</b>	Completed
<b>Publication Details</b>	1. Prashanth NS, Elias MA, Pati MK, Aivalli P, Munegowda CMM, Bhanuprakash S, et al. Improving access to medicines for non-communicable diseases in rural India: a mixed methods study protocol using quasi-experimental design. BMC Health Serv Res [Internet]. 2016 Dec 22;16(1):421. 2. Elias MA, Pati MK, Aivalli P, Srinath B, Munegowda C, Shroff ZC, et al. Preparedness for delivering noncommunicable disease services in primary care: Access to medicines for diabetes and hypertension in a district in south India. BMJ Glob Heal. 2017; 3. Aivalli PK, Elias MA, Pati MK, Bhanuprakash S, Munegowda C, Shroff ZC, et al. Perceptions of the quality of generic medicines: implications for trust in public services within the local health system in Tumkur, India. BMJ Glob Heal. 2018;
<b>Brief Summary</b>	This is a health systems research study in which we have enrolled 39 primary health centres in three talukas of Tumkur district into one of three arms of the study (two intervention and one control). No patients or human subjects are being enrolled in the study. However, the primary outcomes of interest are related to non-communicable disease outcomes in the community, which is being measured before and after the intervention using a cluster-randomised sampling design in each of these facilities. The intervention includes a package of activities provided to health workers.