



Clinical Trial Details (PDF Generation Date :- Wed, 24 Feb 2021 17:23:16 GMT)

CTRI Number	CTRI/2013/10/004049 [Registered on: 07/10/2013] - Trial Registered Retrospectively	
Last Modified On	22/11/2019	
Post Graduate Thesis	No	
Type of Trial	Interventional	
Type of Study	Behavioral	
Study Design	Cluster Randomized Trial	
Public Title of Study	Diet and lifestyle InterventionS through Anganwadi Workers and Accredited Social Health Activists (DISHA)	
Scientific Title of Study	Effectiveness of diet and lifestyle intervention through Information Education Communication (IEC) tools with Angan Wadi Centres (AWCs) as the centre of knowledge dissemination for hypertension (including hypercholesterolemia and diabetes) risk reduction – 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	
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Source of Monetary or Material Support	Source of Monetary or Material Support			
	> Indian Council of Medical Research			
Primary Sponsor	Primary Sponsor Details			
	Name	Indian Council of Medical Research		
	Address	Indian Council of Medical Research Ansari Nagar, New Delhi - 110029		
	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
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Details of Ethics Committee

Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
Dr Rajendra Prasad Government Medical College and Hospital, Institutional Ethics Committee	Approved	16/11/2011	No
Ethics Committee, Indira Gandhi Hospital, Shimla	Approved	08/12/2011	No
Pondicherry Institute of Medical Sciences	Approved	07/10/2011	No
Prince Aly Khan Hospital, Junagarh	Approved	19/10/2011	No
Sri Aurobindo Institute of Medical Sciences Institutional Ethics Committee	Approved	07/08/2013	No

Regulatory Clearance Status from DCGI

Status	Date
Not Applicable	No Date Specified

Health Condition / Problems Studied

Health Type	Condition
Healthy Human Volunteers	NCD risk-factor assessment of community participants is conducted, followed by a health-promotion intervention in intervention clusters. Change in population level blood pressure will be assessed.

Intervention / Comparator Agent

Type	Name	Details
Intervention	DISHA (Diet and lifestyle InterventionS for Hypertension risk-reduction through Anganwadi Workers and accredited social health activists) Intervention	This is a diet and lifestyle intervention delivered by Anganwadi Workers & ASHAs for 18 months at individual, group & mass level to reduce hypertension risk in their communities by using Information Education Communication (IEC) as tools for 1) Reducing salt & oil consumption 2) Increasing dietary fibre intake 3) Increasing physical activity 4) Reducing



		alcohol & tobacco consumption. In both treatment clusters standard regimen for control of diabetes, hypertension & dyslipidemia including counselling for life style modification will be followed as medically indicated .But intensity of intervention would differ in the two groups. In intervention clusters, intense IEC would be given for 18 months, whereas, in control clusters, usual IEC would be imparted.
Comparator Agent	Usual IEC Intervention	Control Clusters will receive usual(common) IEC intervention

Inclusion Criteria

Inclusion Criteria	
Age From	18.00 Year(s)
Age To	99.00 Year(s)
Gender	Both
Details	Any individual, irrespective of gender, who is more than 18 years of age, and permanently resides in the household will be approached to participate in this study for cardiovascular risk-factor assessment.

Exclusion Criteria

Exclusion Criteria	
Details	This study proposes to study adults in the community to assess cardiovascular risk-factor prevalence in the community, and excludes adults below the age of 18 years. Additional exclusions are: <ul style="list-style-type: none"> • Pregnant women • Bed-ridden individuals • Persons who are unable to comprehend the interview questionnaire (Reasons for exclusion will be documented)

Method of Generating Random Sequence

Computer generated randomization

Method of Concealment

Centralized

Blinding/Masking

Open Label

Primary Outcome

Outcome	Timepoints
The primary outcome will be difference between the changes in population level blood pressure between intervention and control clusters.	18 months

Secondary Outcome

Outcome	Timepoints
-Operational feasibility of integrating NCD risk reduction in community health programs through existing community level healthcare volunteers such as ASHA or equivalent. -Usefulness of trained healthcare workers to affect changes in dietary fat, fibre and salt, tobacco and alcohol consumption and increasing physical activity.	18 months



	-Efficacy of the IEC intervention to evaluate changes in lipid levels and glycemia.
Target Sample Size	Total Sample Size=18000 Sample Size from India=18000 Final Enrollment numbers achieved (Total)=25128 Final Enrollment numbers achieved (India)=25128
Phase of Trial	Phase 3
Date of First Enrollment (India)	10/11/2012
Date of First Enrollment (Global)	No Date Specified
Estimated Duration of Trial	Years=3 Months=0 Days=0
Recruitment Status of Trial (Global)	Not Applicable
Recruitment Status of Trial (India)	Completed
Publication Details	Jeemon P, Narayanan G, Kondal D, Kahol K, Bharadwaj A, Purty A, Negi P, Ladhani S, Sanghvi J, Singh K, Kapoor D, Sobti N, Lall D, Manimunda S, Dwivedi S, Toteja G, Prabhakaran D; DISHA Study Investigators. Task shifting of frontline community health workers for cardiovascular risk reduction: design and rationale of a cluster randomised controlled trial (DISHA study) in India. BMC Public Health. 2016 Mar 15;16:264.
Brief Summary	<p>The primary goal of the present study is to assess the effectiveness of intense versus usual Information Education Communication (IEC) interventions on diet and lifestyle modifications delivered by existing community-level health-workers (Anganwadi workers or ASHAs or equivalent) on population level blood pressure; the aim being assessment of operational feasibility of integrating NCD risk reduction in community health programs through existing community level healthcare volunteers such as Anganwadi Workers or ASHAs (community health workers – CHWs).</p> <p>This feasibility study specifically aims to assess the usefulness of trained CHWs to facilitate changes in dietary fat, fibre and salt, tobacco and alcohol consumption and increasing physical activity at the community level in the Indian rural and urban health systems setting. The efficacy of these interventions to evaluate clinical indicators namely changes in lipid levels and glycemia will also be assessed.</p> <p>This study is a collaborative effort between Centre for Chronic Disease Control (CCDC, New Delhi) and 5 participating sites, namely Pondicherry Institute of Medical Science (Pondicherry), Dr. Rajendra Prasad Government Medical College (Tanda); Indira Gandhi Medical College (Shimla) and Aga Khan Health Services (Mumbai with study site in Junagadh).</p>

