



Clinical Trial Details (PDF Generation Date :- Sun, 29 Nov 2020 12:26:06 GMT)

CTRI Number	CTRI/2020/07/026796 [Registered on: 25/07/2020] - Trial Registered Prospectively	
Last Modified On	24/07/2020	
Post Graduate Thesis	No	
Type of Trial	Interventional	
Type of Study	Behavioral Other (Specify) [Provision of cotton face masks]	
Study Design	Cluster Randomized Trial	
Public Title of Study	A trial to evaluate the effect of cotton face-masks and other behavioral factors on COVID-19 risk in rural Telangana	
Scientific Title of Study	Effect of cotton face-masks and other behavioral and health-related risk factors on COVID-19 incidence and severity: Pragmatic cluster-randomized trial and nested observational study in 45 villages in Telangana	
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			
	> Synergy India Foundation, TSWREIS DSS BHAVAN, 4TH floor, Opposite Chacha Nehru Park, Masabtank, Hyderabad			
Primary Sponsor	Primary Sponsor Details			
Name	National Institute of Nutrition			
Address	Jamai Osmania PO, Hyderabad 500007			
Type of Sponsor	Research institution			
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
	Bharati Kulkarni	National Institute Of Nutrition	Clinical Division, Ground Floor, National Institute Of Nutrition, Jamai Osmania, Hyderabad.Telangana Hyderabad Hyderabad TELANGANA	40-27197256 dr.bharatikulkarni@gmail.com
Details of Ethics Committee	Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
	Institutional Ethics committee, National Institute of Nutrition (IEC-NIN)	Approved	17/07/2020	No
Regulatory Clearance Status from DCGI	Status		Date	
	Not Applicable		No Date Specified	
Health Condition / Problems Studied	Health Type		Condition	
	Healthy Human Volunteers		COVID-19	
Intervention / Comparator Agent	Type	Name	Details	
	Intervention	Cloth Mask	Two masks per individual will be provided to the participants of intervention village	
	Comparator Agent	No intervention	Nil	
Inclusion Criteria	Inclusion Criteria			
	Age From	18.00 Year(s)		
	Age To	99.00 Year(s)		
	Gender	Both		
	Details	All adults above 18 years of age will be eligible.		
Exclusion Criteria	Exclusion Criteria			
	Details	Village level: If a face mask intervention is ongoing in a village or village leaders decline to give permission Individual level: Seriously/ terminally ill patients, chronic lung		



	conditions and mentally challenged patients will be excluded from the study.	
Method of Generating Random Sequence	Computer generated randomization	
Method of Concealment	Centralized	
Blinding/Masking	Open Label	
Primary Outcome	Outcome	Timepoints
	Village-level incidence of COVID-19	weekly upto 6 months
Secondary Outcome	Outcome	Timepoints
	Seroprevalence of SARS-CoV-2 antibodies	At the end of 6 months
Target Sample Size	Total Sample Size=10000 Sample Size from India=10000 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)	03/08/2020	
Date of First Enrollment (Global)	No Date Specified	
Estimated Duration of Trial	Years=0 Months=6 Days=0	
Recruitment Status of Trial (Global)	Not Applicable	
Recruitment Status of Trial (India)	Not Yet Recruiting	
Publication Details	NIL	
Brief Summary	<p><small>Use of face mask or suggested face covering when outside the home is made mandatory in India as an attempt to reduce the transmission of COVID-19. However, there is a lack of evidence regarding the effectiveness of people using face covering like, scarf or mask. Also, the factors associated with the incidence of the disease and severity is still unclear.</small></p> <p><small>Therefore, through this study, we wish to study the effectiveness of using face masks (2 per person) over the routine face covering used by assessing the village-level incidence of COVID-19 between the two study arms. We also look for the socio-demographic, behavioral (disturbance, hygiene and physical distancing) and health (chronic condition like diabetes and infectious disease like malaria and tuberculosis) factors associated with the incidence of the disease.</small></p> <p><small>The results of the study would help the policy makers in developing efficient resource allocation strategies, to design and implement the interventions, and targeting/ shielding the high risk groups to control the COVID-19 pandemic.</small></p>	