



Clinical Trial Details (PDF Generation Date :- Tue, 24 Nov 2020 05:24:55 GMT)

<b>CTRI Number</b>	CTRI/2020/07/026796 [Registered on: 25/07/2020] - <b>Trial Registered Prospectively</b>		
<b>Last Modified On</b>	24/07/2020		
<b>Post Graduate Thesis</b>	No		
<b>Type of Trial</b>	Interventional		
<b>Type of Study</b>	Behavioral Other (Specify) [Provision of cotton face masks]		
<b>Study Design</b>	Cluster Randomized Trial		
<b>Public Title of Study</b>	A trial to evaluate the effect of cotton face-masks and other behavioral factors on COVID-19 risk in rural Telangana		
<b>Scientific Title of Study</b>	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		
<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>Source of Monetary or Material Support</b>	<b>Source of Monetary or Material Support</b>			
	> Synergy India Foundation, TSWREIS DSS BHAVAN, 4TH floor, Opposite Chacha Nehru Park, Masabtank, Hyderabad			
<b>Primary Sponsor</b>	<b>Primary Sponsor Details</b>			
	<b>Name</b>	National Institute of Nutrition		
	<b>Address</b>	Jamai Osmania PO, Hyderabad 500007		
	<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>
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<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>
	Institutional Ethics committee, National Institute of Nutrition (IEC-NIN)	Approved	17/07/2020	No
<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		COVID-19	
<b>Intervention / Comparator Agent</b>	<b>Type</b>	<b>Name</b>	<b>Details</b>	
	Intervention	Cloth Mask	Two masks per individual will be provided to the participants of intervention village	
	Comparator Agent	No intervention	Nil	
<b>Inclusion Criteria</b>	<b>Inclusion Criteria</b>			
	<b>Age From</b>	18.00 Year(s)		
	<b>Age To</b>	99.00 Year(s)		
	<b>Gender</b>	Both		
	<b>Details</b>	All adults above 18 years of age will be eligible.		
<b>Exclusion Criteria</b>	<b>Exclusion Criteria</b>			
	<b>Details</b>	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.	
<b>Method of Generating Random Sequence</b>	Computer generated randomization	
<b>Method of Concealment</b>	Centralized	
<b>Blinding/Masking</b>	Open Label	
<b>Primary Outcome</b>	<b>Outcome</b>	<b>Timepoints</b>
	Village-level incidence of COVID-19	weekly upto 6 months
<b>Secondary Outcome</b>	<b>Outcome</b>	<b>Timepoints</b>
	Seroprevalence of SARS-CoV-2 antibodies	At the end of 6 months
<b>Target Sample Size</b>	<b>Total Sample Size=10000</b> <b>Sample Size from India=10000</b> <b>Final Enrollment numbers achieved (Total)=Applicable only for Completed/Terminated trials</b> <b>Final Enrollment numbers achieved (India)=Applicable only for Completed/Terminated trials</b>	
<b>Phase of Trial</b>	N/A	
<b>Date of First Enrollment (India)</b>	03/08/2020	
<b>Date of First Enrollment (Global)</b>	No Date Specified	
<b>Estimated Duration of Trial</b>	<b>Years=0</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>	Not Yet Recruiting	
<b>Publication Details</b>	NIL	
<b>Brief Summary</b>	<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>	