



Clinical Trial Details (PDF Generation Date :- Fri, 14 Aug 2020 09:59:51 GMT)

<b>CTRI Number</b>	CTRI/2020/05/025320 [Registered on: 22/05/2020] - <b>Trial Registered Prospectively</b>		
<b>Last Modified On</b>	22/05/2020		
<b>Post Graduate Thesis</b>	No		
<b>Type of Trial</b>	Interventional		
<b>Type of Study</b>	Yoga & Naturopathy		
<b>Study Design</b>	Non-randomized, Active Controlled Trial		
<b>Public Title of Study</b>	Effect of Yoga & Naturopathy in patients with COVID-19		
<b>Scientific Title of Study</b>	NATUROPATHY AND YOGA IN THE MANAGEMENT OF COVID19 A Multi-center controlled clinical trial		
<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>		
	<b>Name</b>	Manavalan Narayanaswamy	
	<b>Designation</b>	Principal	
	<b>Affiliation</b>	Government Yoga AND Naturopathy Medical College	
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		<b>Name</b>	Manavalan Narayanaswamy
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**Source of Monetary or Material Support**

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> Indian Naturopathy And Yoga Graduates Medical Association, 119, parasurama Easwaran Kovil North Mada Street, Ayanavaram, Chennai-600023

**Primary Sponsor**

Primary Sponsor Details	
<b>Name</b>	Government Yoga And Naturopathy Medical College Chennai
<b>Address</b>	Arumbakkam, Chennai
<b>Type of Sponsor</b>	Government medical college

**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 P Vasanthamani	Kilpauk Medical College Hospital	Department of Medicine, Kilpauk Medical College, Chennai Chennai TAMIL NADU	04426412979  dean@gkmc.in
Dr Narayana Babu	Omandurar Medical College Hospital	Department of Medicine, Omandurar Medical College Hospital, Chennai Chennai TAMIL NADU	04425333317  gmcomandurar@gmail.com
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Dr B Balaji	Stanley Medical College Hospital	Department of Medicine, Stanley Medical College, Chennai Chennai TAMIL NADU	04425282350  Stanleyhospital@gmail.com

**Details of Ethics Committee**

Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
Government Yoga And Naturopathy Medical College	Approved	02/05/2020	No
IEC, Kilpauk Medical College, Chennai	Submitted/Under Review	No Date Specified	No
IEC, Madras Medical College, Chennai	Submitted/Under Review	No Date Specified	No
IEC, Stanley Medical Collge, Chennai	Approved	14/05/2020	No
Institutional Ethics Committee, Omandurar	Approved	22/05/2020	No



	Medical Collge, chennai		
<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>	
	Patients	Coronavirus as the cause of diseases classified elsewhere	
<b>Intervention / Comparator Agent</b>	<b>Type</b>	<b>Name</b>	<b>Details</b>
	Intervention	Yoga & Naturopathy immune boosting and stress management protocol	Essential: 1. Natural immune boosting fresh juice: Indian Gooseberry juice – 50ml Basil Juice – 50ml Ginger Juice – 10ml Fresh Lime juice – 5ml Turmeric powder – ¼ tsp Water – 150 ml (Morning) 2. Natural immune boosting hot drink: Peeled Crushed Ginger 5 gm, Tulsi (Basil) leaves 10 gms, Pepper powder ¼ tsp, Crushed Adhimaduram 5 gms (liquorice root), Turmeric powder ¼ tsp and drinking water 250 ml (Evening). 3. Yoga: Vajrasana, Bhastrika, Brahmari, Quick relaxation technique, Deep relaxation technique, Jala Neti (twice/thrice a day) Care as indicated by Y&N physician 1. Hot water gargling: Taking 30-50 ml of water and whirl it around pharynx & oral cavity. 2. Steam inhalation: Inhalation of steam with or without essential oils for 5-10 minutes. 3. Sun bath: Sun exposure (10 minutes) in the morning and in the evening 4. Aromatherapy (Eucalyptus/peppermint/thyme/lavendar/basil): 1-2 drops in tissue paper or mix with gingely oil & apply over nose and neck. These treatments will be given from enrollment till 14 days post-confirmation of infection
	Comparator Agent	Standard Care	Standard care as per local protocol
<b>Inclusion Criteria</b>	<b>Inclusion Criteria</b>		
	<b>Age From</b>	18.00 Year(s)	
	<b>Age To</b>	75.00 Year(s)	
	<b>Gender</b>	Both	
	<b>Details</b>	a) Written informed consent prior to performing study procedures. Witnessed oral consent will be accepted in order to avoid paper handling. Written consent by patient or their family members will be obtained wherever applicable. b) Male or Female adult patient ?18 years and ?75 years of age at the time of recruitment c) Has laboratory-confirmed SARS-CoV-2 infection as determined by PCR in naso/oropharyngeal swabs or any other relevant specimen	



	d) Asymptomatic / uncomplicated illness / mild pneumonia COVID-19 as defined by ICMR	
<b>Exclusion Criteria</b>	<b>Exclusion Criteria</b>	
	<b>Details</b>	a) Explicit non-willingness to be a part of the research study b) Patients with moderate/severe stages of COVID19 c) Participation in any other clinical trials
<b>Method of Generating Random Sequence</b>	Not Applicable	
<b>Method of Concealment</b>	Not Applicable	
<b>Blinding/Masking</b>	Not Applicable	
<b>Primary Outcome</b>	<b>Outcome</b>	<b>Timepoints</b>
	Time to progress to next stage of severity i.e., from asymptomatic/uncomplicated/mild pneumonia to moderate/severe stages	At 15 days
<b>Secondary Outcome</b>	<b>Outcome</b>	<b>Timepoints</b>
	Clinical endpoints 1. Time to All-cause mortality at discharge 2. All-cause mortality at 28 days Measures of morbidity 1. Number of days lived with infection 2. Number of days lived with intensive care if the disease has progressed to severe infection from asymptomatic, mild, and moderate stages. 3. Measuring the symptoms using standard scores Patient reported outcome 1. Quality of life as assessed by WHO-QoL BREF 2. Anxiety as assessed by GAD scale Safety outcomes	At Discharge
<b>Target Sample Size</b>	<b>Total Sample Size=658</b> <b>Sample Size from India=658</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>	Phase 3/ Phase 4	
<b>Date of First Enrollment (India)</b>	22/05/2020	
<b>Date of First Enrollment (Global)</b>	No Date Specified	
<b>Estimated Duration of Trial</b>	<b>Years=0</b> <b>Months=4</b> <b>Days=0</b>	
<b>Recruitment Status of Trial (Global)</b>	Not Applicable	
<b>Recruitment Status of Trial (India)</b>	Open to Recruitment	
<b>Publication Details</b>	Nil	
<b>Brief Summary</b>	YONAC trial is a multi-centre controlled trial aimed at improving outcomes in patients diagnosed with COVID19 with Yoga & Naturopathy treatment modalities which includes a natural immune boosting fresh juice (, natural immune boosting hot drink and Yoga. In addition, based on the need, hot water gargling, steam inhalation, essential oil (eucalyptus/peppermint/thyme/lavendar/basil), self acupressure will be provided to the patients.	