



Clinical Trial Details (PDF Generation Date :- Fri, 14 Aug 2020 11:26:00 GMT)

<b>CTRI Number</b>	CTRI/2020/06/025714 [Registered on: 08/06/2020] - <b>Trial Registered Prospectively</b>	
<b>Last Modified On</b>	31/05/2020	
<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>	Holistic Health Management through Yoga and Naturopathy for Frontline COVID Health Care Providers – The H2M trial	
<b>Scientific Title of Study</b>	Holistic Health Management through Yoga and Naturopathy for Frontline COVID Health Care Providers – The H2M 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>	Dr Manavalan Narayanaswamy
	<b>Designation</b>	Principal
	<b>Affiliation</b>	Government Yoga AND Naturopathy Medical College
	<b>Address</b>	Department of Naturopathy, Government Yoga & Naturopathy Medical College, Arignar Anna Indian Medicine Campus Arumbakkam, Chennai Chennai TAMIL NADU 600106 India Chennai TAMIL NADU 600106 India
	<b>Phone</b>	
	<b>Fax</b>	
	<b>Email</b>	gynmcchennai@gmail.com
<b>Details Contact Person (Scientific Query)</b>	<b>Details Contact Person (Scientific Query)</b>	
	<b>Name</b>	Dr Manavalan Narayanaswamy
	<b>Designation</b>	Principal
	<b>Affiliation</b>	Government Yoga AND Naturopathy Medical College
	<b>Address</b>	Department of Naturopathy, Government Yoga & Naturopathy Medical College, Arignar Anna Indian Medicine Campus Arumbakkam, Chennai Chennai TAMIL NADU 600106 India  TAMIL NADU 600106 India
	<b>Phone</b>	
	<b>Fax</b>	
	<b>Email</b>	gynmcchennai@gmail.com
<b>Details Contact Person (Public Query)</b>	<b>Details Contact Person (Public Query)</b>	
	<b>Name</b>	Dr Manavalan Narayanaswamy
	<b>Designation</b>	Principal
	<b>Affiliation</b>	Government Yoga AND Naturopathy Medical College
	<b>Address</b>	Department of Naturopathy, Government Yoga & Naturopathy Medical College, Arignar Anna Indian Medicine Campus Arumbakkam, Chennai Chennai TAMIL NADU 600106 India  TAMIL NADU



	600106 India			
<b>Phone</b>				
<b>Fax</b>				
<b>Email</b>	gynmcchennai@gmail.com			
<b>Source of Monetary or Material Support</b>	<b>Source of Monetary or Material Support</b>			
	> Indian Naturopathy And Yoga Graduates Medical Association, 119, parasurama Easwaran Kovil North Mada Street, Ayanavaram, Chennai-600023			
<b>Primary Sponsor</b>	<b>Primary Sponsor Details</b>			
<b>Name</b>	Government Yoga And Naturopathy Medical College and Hospital Chennai			
<b>Address</b>	Arumbakkam, Chennai			
<b>Type of Sponsor</b>	Government medical college			
<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 Babu	Government Medical College Omandurar estate	Department of Medicine, Omandurar Medical College Hospital, Chennai Chennai TAMIL NADU Chennai TAMIL NADU	04425333317  gmcomandurar@gmail.com
	Dr N Manavalan	Government Yoga & Naturopathy Medical Collge & Hospital	Department of Naturopathy, Government Yoga & Naturopathy Medical College & Hospital, Arignar Anna Indian Medicine Campus, Arumbakkam, Chennai Chennai TAMIL NADU	9840128684  gynmcchennai@gmail.com
	Dr B Balaji	Stanley Medical College Hospital	Department of Medicine, Stanley Medical College, Chennai Chennai TAMIL NADU Chennai TAMIL NADU	04425282350  stanleyhospital@gmail.com
<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>
	IEC, GYNMC, Chennai	Approved	08/05/2020	No
	Institutional Ethics Committee, Omandurar Medical Collge, chennai	Approved	22/05/2020	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	Doctors and healthcare workers working in COVID19 prevention and clinical wards	
<b>Intervention / Comparator Agent</b>	<b>Type</b>	<b>Name</b>	<b>Details</b>
	Intervention	Yoga & Naturopathy	1. Prevalidated scientific yoga module comprising of asanas, pranayama, relaxation and meditation would be administered by a Government Yoga and Naturopathy physician for 6 days a week for 4 weeks as a recorded video. 2. A set of 5 simple lifestyle modification tips would be recommended to be followed by the participants in the a. Drinking 1.5 – 2 litres of water everyday b. Practicing mental silence for 10 minutes everyday c. Diet to include sprouts, greens and vegetables daily and Making one meal a complete fruit diet atleast once a week d. Hot water with salt and turmeric gargling once a day e. Including natural immune boosting fresh juice (made of Indian Gooseberry, Ginger, Turmeric,tulsi and lemon) and natural immune boosting hot drink (made of ginger, tulsi, pepper, liquorice, turmeric) once a day.
	Comparator Agent	Usual care	Usual care / No intervention
<b>Inclusion Criteria</b>	<b>Inclusion Criteria</b>		
	<b>Age From</b>	18.00 Year(s)	
	<b>Age To</b>	70.00 Year(s)	
	<b>Gender</b>	Both	
	<b>Details</b>	1. Doctors and healthcare workers of all ages irrespective of gender 2. Willingness to participate	
<b>Exclusion Criteria</b>	<b>Exclusion Criteria</b>		
	<b>Details</b>	Confirmed diagnosis of COVID-19 Explicit non-willingness to participate in the study	
<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>
	1. Perseverative Thinking Questionnaire 2. GAD7 Questionnaire 3. Pittsburg Sleep Quality Index 4. Freiburg Mindfulness Inventory 5. Qualitative assessments for Subjective perception of Stress and Yoga		15 days and 4 weeks



<b>Secondary Outcome</b>	<table border="1"> <thead> <tr> <th>Outcome</th> <th>Timepoints</th> </tr> </thead> <tbody> <tr> <td>2. GAD7 Questionnaire 3. Pittsburg Sleep Quality Index 4. Freiburg Mindfulness Inventory 5. Qualitative assessments for Subjective perception of Stress and Yoga</td> <td>15 days and 4 weeks</td> </tr> </tbody> </table>	Outcome	Timepoints	2. GAD7 Questionnaire 3. Pittsburg Sleep Quality Index 4. Freiburg Mindfulness Inventory 5. Qualitative assessments for Subjective perception of Stress and Yoga	15 days and 4 weeks
Outcome	Timepoints				
2. GAD7 Questionnaire 3. Pittsburg Sleep Quality Index 4. Freiburg Mindfulness Inventory 5. Qualitative assessments for Subjective perception of Stress and Yoga	15 days and 4 weeks				
<b>Target Sample Size</b>	<b>Total Sample Size=1200</b> <b>Sample Size from India=1200</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>	02/06/2020				
<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>	Not Yet Recruiting				
<b>Publication Details</b>	Not Applicable				
<b>Brief Summary</b>	As there is no convincing evidence regarding the best strategy to promote mental wellbeing in the COVID19 crisis, we propose to implement Yoga and Naturopathic intervention to the frontline health workers on an in-person / virtual platform to assess its health benefits.				