



Clinical Trial Details (PDF Generation Date :- Mon, 25 Jan 2021 08:40:03 GMT)

<b>CTRI Number</b>	CTRI/2014/03/004460 [Registered on: 10/03/2014] - <b>Trial Registered Prospectively</b>	
<b>Last Modified On</b>	16/03/2020	
<b>Post Graduate Thesis</b>	No	
<b>Type of Trial</b>	Interventional	
<b>Type of Study</b>	Yoga & Naturopathy	
<b>Study Design</b>	Randomized, Parallel Group Trial	
<b>Public Title of Study</b>	Effect of alternate nostril breathing exercise on induced anxiety	
<b>Scientific Title of Study</b>	Effect of alternate nostril breathing exercise on induced anxiety	
<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 Ashwin Kamath
	<b>Designation</b>	Associate Professor
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<b>Source of Monetary or Material Support</b>	<b>Source of Monetary or Material Support</b>			
	> Manipal University			
<b>Primary Sponsor</b>	<b>Primary Sponsor Details</b>			
	<b>Name</b>	Kasturba Medical College Mangalore		
	<b>Address</b>	Kasturba Medical College, Light house hill road, Mangalore - 575001		
	<b>Type of Sponsor</b>	Private 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>
	Ashwin Kamath	Kasturba Medical College	Dept. of Pharmacology, Kasturba Medical College, Light house hill road, Mangalore - 575001 Dakshina Kannada KARNATAKA	9844262808 ashwin.kamath@manipal.edu
<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, Kasturba medical college, Mangalore	Approved	18/09/2013	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		Healthy subjects	
<b>Intervention / Comparator Agent</b>	<b>Type</b>	<b>Name</b>	<b>Details</b>	
	Intervention	Alternate nostril breathing exercise followed by simulated public speaking	Alternate nostril breathing exercise performed for 15 minutes	
	Comparator Agent	No exercise followed by simulated public speaking	Sitting comfortably in a quiet room for 15 minutes	
<b>Inclusion Criteria</b>	<b>Inclusion Criteria</b>			
	<b>Age From</b>	19.00 Year(s)		
	<b>Age To</b>	24.00 Year(s)		
	<b>Gender</b>	Both		
	<b>Details</b>	Healthy subjects		
<b>Exclusion Criteria</b>	<b>Exclusion Criteria</b>			
	<b>Details</b>	1. Practicing any yoga exercises 2. Presence of any acute/chronic illness at the time of participation 3. History of intake of any medication within a week prior to participation in the study		
<b>Method of Generating</b>	Stratified randomization			



<b>Random Sequence</b>		
<b>Method of Concealment</b>	An Open list of random numbers	
<b>Blinding/Masking</b>	Open Label	
<b>Primary Outcome</b>	<b>Outcome</b>	<b>Timepoints</b>
	Anxiety level as measured by visual analog mood scale (VAMS) and self statements during public speaking scale (SSPS)	15 minutes before intervention (baseline); 15, 29, 37 and 55 minutes from the start of intervention
<b>Secondary Outcome</b>	<b>Outcome</b>	<b>Timepoints</b>
	None	None
<b>Target Sample Size</b>	<b>Total Sample Size=30</b> <b>Sample Size from India=30</b> <b>Final Enrollment numbers achieved (Total)=0</b> <b>Final Enrollment numbers achieved (India)=30</b>	
<b>Phase of Trial</b>	N/A	
<b>Date of First Enrollment (India)</b>	01/04/2014	
<b>Date of First Enrollment (Global)</b>	No Date Specified	
<b>Estimated Duration of Trial</b>	<b>Years=1</b> <b>Months=0</b> <b>Days=0</b>	
<b>Recruitment Status of Trial (Global)</b>	Not Applicable	
<b>Recruitment Status of Trial (India)</b>	Completed	
<b>Publication Details</b>	Kamath A, Urval RP, Shenoy AK. Effect of Alternate Nostril Breathing Exercise on Experimentally Induced Anxiety in Healthy Volunteers Using the Simulated Public Speaking Model: A Randomized Controlled Pilot Study. Biomed Res Int. 2017;2017:2450670. doi:10.1155/2017/2450670	
<b>Brief Summary</b>	<p>Anxiolytic potential of drugs have been tested in human experimental models using psychological means. Environmental stimuli or contexts have been used in healthy volunteers to induce anxiety under ethical conditions. Although the level of anxiety induced is low, such studies have yielded valuable results. The objective of the present study is to determine the effect of alternate nostril breathing exercise on various anxiety scores using the simulated public speaking model. The practice of alternate nostril breathing, a yoga breathing technique, is traditionally considered to relieve mental unrest and promote physical and mental balance. In the simulated public speaking test the subject is asked to prepare a speech and subsequently speak in front of a video camera when being video-taped. Anxiety scores are recorded at various time intervals during the test. There have been studies to assess the effects of various yoga techniques on specific physiological and cognitive functions including a possible role in treating various anxiety disorders. The present study is an attempt to evaluate the possible anti-anxiety effect of alternate nostril breathing technique using psychometric measures.</p>	