Clinical Trial Details (PDF Generation Date :- Fri, 25 Sep 2020 15:36:21 GMT)

CTRI Number	CTRI/2013/05/003682 [Registered on: 27/05/2013] - **Trial Registered Retrospectively**
Last Modified On	08/05/2020
Post Graduate Thesis	Yes
Type of Trial	Interventional
Type of Study	Yoga & Naturopathy
Study Design	Randomized, Parallel Group Trial
Public Title of Study	Electrophysiological characterisation of yoga nidra and its role in Insomnia (sleeplessness)patients
Scientific Title of Study	Electrophysiological characterisation of yoga nidra and its role in insomnia patients

Secondary IDs if Any

Secondary ID	Identifier
IESC/T-394/2012	Protocol Number

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
> Nil

Primary Sponsor

Primary Sponsor Details	
Name	All India Institute of Medical Sciences
Address	Department of Physiology New Delhi 110029
Type of Sponsor	Research institution and hospital

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
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Details of Ethics Committee

Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
Institute Ethics Committee, AIIMS	Approved	04/12/2012	No
Last DSMB meeting report	Approved	22/07/2015	No

Regulatory Clearance Status from DCGI

Status	Date
Not Applicable	No Date Specified

Health Condition / Problems Studied

Health Type	Condition
Healthy Human Volunteers	Electrophysiological characterisation of yoga nidra would be done on healthy subjects
Patients	Insomnia (to study the role of yoga nidra in insomnia patients)

Intervention / Comparator Agent

Type	Name	Details
Intervention	Group II (insomnia patients) subgroup B- Yoga Nidra	The intervention group would consist of insomnia patients and they would be given yoga nidra training for four weeks. Their conventional treatment as prescribed by the doctor would not be stopped during the study. Yoga nidra training would be supervised for first five days at the department daily. Each session would be for half an hour and after five supervised sessions, the patient would do this training session on his own for four weeks total duration. The training session would be done by a simple to follow

		pre-recorded CD which would be also given to the patient after the first five days of training.
Comparator Agent	Group II (insomnia patients) subgroup A-Standard treatment	The comparator group would consist of insomnia patients and they also would be studied after four weeks using standard treatment. The standard treatment in the form of Cognitive Behavioural Therapy (CBT) for insomnia would be done in a total of six sessions in four weeks by a CBT trained person.Their treatment as prescribed by the doctor would also continue during the study.
Intervention	Group I (Healthy subjects)	The group I would be studied for electrophysiological characterisation of yoga nidra where healthy subjects would be studied. Baseline electrophysiological monitoring of these subjects using EEG, EOG and EMG would be done. After this, the subjects would be trained in yoga nidra for 4 weeks and electrophysiological monitoring would be repeated at the end of four weeks. The baseline monitoring would be compared with the electrophysiological monitoring obtained after 4 weeks. Yoga nidra training would be supervised for the first five days at the departement. Each session would be of half an hour duration and after five days of supervised sessions the subject would do the training on his own for a total duration of 4 weeks.The training session is done by a simple to follow pre-recorded CD which would be given to patient after five days of traing.

Inclusion Criteria

Inclusion Criteria	
Age From	25.00 Year(s)
Age To	60.00 Year(s)
Gender	Both
Details	Group I Healthy subjects willing to participate in the study would be recruited. They should be following usual wake sleep schedule. Group II Patients should be following usual sleep wake schedule during the study period. They should be symptomatic for atleast six months. They should be having atleast one sleep symptom and one wake symptom for diagnosis of insomnia . Sleep symptom of difficulty initiating/ maintaining sleep/ early morning awakening or non

	restorative or non refreshing sleep, or combination of these sleep symptoms. Wake symptom comprising of sleep associated day time impairment e.g. sleepiness, fatigue, mood disturbances, cognitive difficulties, social impairment or occupational impairment.

Exclusion Criteria

Exclusion Criteria	
Details	History of any acute illness in the preceding one month which is likely to cause sleep disturbance would be considered exclusion criteria. Insomnia patients with symptoms for less than six months would be excluded from the study.

Method of Generating Random Sequence	Coin toss, Lottery, toss of dice, shuffling cards etc
Method of Concealment	Centralized
Blinding/Masking	Outcome Assessor Blinded

Primary Outcome

Outcome	Timepoints
Group I Electrophysiological monitoring using EEG, EMG, EOG, Pre Sleep Arousal Scale Salivary Cortisol Group II Overnight Polysomnography Insomnia severity index Pittsburgh Sleep Quality Index Pre Sleep Arousal Scale Salivary Cortisol	Baseline and after 4 weeks

Secondary Outcome

Outcome	Timepoints
Group II- Insomnia severity index Pre Sleep Arousal Scale Salivary Cortisol	2 weeks
Group I- Pre sleep arousal scale, salivary cortisol	2 weeks

Target Sample Size	**Total Sample Size=**90 **Sample Size from India=**90 **Final Enrollment numbers achieved (Total)=**90 **Final Enrollment numbers achieved (India)=**90
Phase of Trial	N/A
Date of First Enrollment (India)	28/02/2013
Date of First Enrollment (Global)	No Date Specified
Estimated Duration of Trial	**Years=**2 **Months=**0 **Days=**0
Recruitment Status of Trial (Global)	Not Applicable
Recruitment Status of Trial (India)	Completed
Publication Details	Yoga Nidra: An innovative approach for management of chronic insomnia-A case report K Datta, M Tripathi, HN Mallick - Sleep Science and Practice, 2017
Brief Summary	The study is a PhD thesis work which would be to do electrophysiological characterisation of yoga nidra and to study its role in insomnia patients. Introduction- According to ancient literature, yoga nidra is also called yogic sleep. Yoga nidra has been used in some diseases eg. Diabetes mellitus, post traumatic stress disorder, patients with menstrual abnormality, anxiety and depression. Although there is a mention of yoga nidra in ancient literature and it has been used for diseases, but no literature is available on its electrophysiological characterisation and its role in sleep disorders. This study aims to study its role in insomnia patients. Material and Methods-The study would be done in two groups- group I would be done on 30 healthy subjects where electrophysiological monitoring while doing yoga nidra training after 4 weeks of training and would be compared to baseline at the same time of the day. Pre sleep arousal scale and salivary cortisol would be collected at baseline and after 4 weeks. This would be a longitudinal study design.

Group II would be to study the role of yoga nidra in insomnia patients in a randomised control design. This would be done on 60 insomnia patients randomly divided into two subgroups consisting of 30 patients each in each subgroup- Subgroup A and Subgroup B. Subgroup A would be treated with conventional treatment and subgroup B would be treated with conventional treatment and yoga nidra. Patients would be offered overnight polysomnography before and after the intervention. They would also complete questionnaires assessing their sleep quality, and those monitoring treatment outcomes. Salivary estimation of cortisol would be done during the course of the intervention.

The data collected would be analysed using statistical measures.