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Yoga for heart attack and sleep quality

Submission date	Recruitment status	[ ] Prospectively registered
20/03/2024	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
07/05/2024	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
08/04/2024	Circulatory System	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Sleep disorders are common in patients with cardiovascular diseases. Poor sleep quality increases health risks such as hypertension, atrial fibrillation, metabolic syndrome and stroke. Cognitive-behavioural therapy is the first-line treatment for chronic insomnia, but it has accessibility and adherence challenges. Sleep medications have side effects. Studies have reported that Yoga asana and meditation improve sleep and reduce stress, diabetes onset and cardiovascular risks. Yoga Nidra is a yogic relaxation technique that provides deep psychological and physical relaxation. It has been shown to improve sleep quality and reduce stress and blood pressure. However, no studies have demonstrated the benefit of Yoga Nidra in patients with coronary artery disease and poor sleep quality. This study aims to determine the effect of Yoga Nidra in treating coronary artery disease patients with poor sleep quality.

Who can participate?
Patients with coronary artery disease of both sexes, aged between 30-80 years old

What does the study involve?
All the participants recruited for the study will be randomly allocated into two groups: the Intervention group (Yoga Nidra + Sleep Hygiene) and the Control group (Sleep Hygiene). Participants allocated to the Intervention group will be subjected to Yoga Nidra sessions for 3 months, in addition to sleep hygiene education and the standard guideline-recommended therapy. Participants in the control group will receive standard guideline-recommended therapy along with sleep hygiene education over 3 months. All the participants will be subjected to an assessment of sleep parameters using an actigraphy device (need to wear a wrist-watch like a device recording sleep duration and quality), Ambulatory blood pressure monitoring (a device to monitor Blood pressure), and echocardiography will be recorded at the baseline visit and after three months. Questionnaires assessing quality of life (SF-36 questionnaire), mental health (Beck's anxiety and depression scale), and stress(perceived stress scale) will be assessed

What are the possible benefits and risks of participating?
Practising the Yoga Nidra sessions will help the participants relax, reduce stress, and improve sleep. Participating in the trial has no risk, as the Yoga Nidra practice sessions are reportedly safe.

Where is the study run from?
Department of Cardiology, All India Institute of Medical Sciences, New Delhi, India.
Centre for Integrative Medicine and Research, All India Institute of Medical Sciences, New Delhi, India.

When is the study starting, and how long is it expected to run for?
February 2021 to June 2024

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr. Gautam Sharma, drsharmagautam@aiims.edu

Contact information

Type(s)
Principal investigator

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Type(s)
Public, Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Yoga in coronary artery disease and quality of sleep

Acronym
YOGA-CADETS

Study objectives
The "Yoga Nidra" intervention will improve the quality of sleep in individuals diagnosed with coronary artery disease

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 03/05/2021, Institute Ethics committee for Post Graduate Research (All India Institute of Medical Sciences (AIIMS), Ansari Nagar, New Delhi, 110029, India; +9126594579; ethicscommittee@gmail.com), ref: IECPG- 254/24.03.2021, RT- 11/28.04.2021

Study design
Prospective randomized open-label outcome-assessor-blind single-centre study

Primary study design
Interventional

Study type(s)
Treatment, Efficacy

Health condition(s) or problem(s) studied
ICD-10 condition:125.1, Atherosclerotic heart disease of native coronary artery

Interventions
Eligible participants who give written consent for participation will be randomized into two arms, intervention and comparator groups, using a simple randomization method with an allocation ratio of 1:1. An independent statistician will generate the random allocation sequence. In addition to maintaining concealment, serial number-specific opaque sealed envelopes will be maintained by a person who is not a part of the study. The current study is a non-blinded trial; however, the outcome assessors will be blinded to the allocation of the subjects.

Intervention group: ‘Yoga Nidra’+ 'Sleep hygiene' sessions for three months
Comparator group: 'Sleep hygiene' sessions for three months

Intervention detail: Yoga Nidra is a simple method of relaxation practised in the flat lying position of ‘Shavasana’ (lying on the back, the arms and legs are spread at about 45 degrees) and following the instructions of the trained yoga therapist. The therapist guides the participants into progressively deeper states of relaxation and self-awareness. Participants are instructed to focus on each body part while breathing normally. Participants are asked not to sleep during the session and follow the instructions provided by the yoga instructor. The yoga classes for the patients consist of 30 to 35 minute /day sessions, five days a week. Total nine sessions [three sessions (in-person guidance/contact session) and six sessions (supervised online session). Duration of Yoga Protocol: 30 - 35 minutes.

Sleep hygiene details: An experienced sleep expert will administer the Ten Commandments of Healthy Sleep in a personal interactive session (approximately ten minutes) at baseline.

Intervention Type
Behavioural

Primary outcome(s)
Sleep quality measured using an actigraphy at baseline and after 3 months

Key secondary outcome(s))
The following secondary outcome measures will be assessed at baseline and after 3 months:
1. Total Sleep time (night), total sleep time (24 hours), sleep latency, and Sleep fragmentation index measured using an actigraphy
2. Daytime blood pressure (BP), 24-hour and mean BP reduction, and nocturnal dip in systolic BP measured using ambulatory blood pressure monitoring (ABPM)
3. Diastolic function measured using echocardiography
4. Improvement in quality of life measured using the Short-Form-36 questionnaire (SF 36)
5. Mental well-being measured using Beck's Depression Inventory
6. Reduction in salivary cortisol levels measured using electrochemiluminescence immunoassay (ECLIA)/ enzyme-linked immunosorbent assay(ELISA)/ liquid chromatography-mass spectrometry (LC-MS)
7. Change in angina class, antianginal medications, hospitalization or physician contact for worsening of symptoms measured using clinical interviews

Completion date
30/06/2024

Eligibility

Key inclusion criteria
1. Patient with age group of 30 – 80 years old
2. Both sexes
3. Patient with coronary artery disease, either with Chronic coronary syndrome or after 4 months of Acute coronary syndrome.
4. Patients who are not planned for revascularization.
5. Patients who were revascularized at least 6 weeks back CCS Angina ≤ II.

Participant type(s)

Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
30 years

Upper age limit
80 years

Sex
All

Key exclusion criteria
1. Patients who are regular practitioners of yoga.
2. Patients suffering from any neuro-psychiatric illness.
3. Patients who are unable to lie down still due to any medical condition.
4. Patients who are diagnosed case of Obstructive Sleep Apnea.
5. Patients with Left ventricular ejection fraction (LVEF) less than or equal to 30 %.

Date of first enrolment
22/09/2021

Date of final enrolment
30/03/2024

Locations

Countries of recruitment
India

Study participating centre
Department of Cardiology, All India Institute of Medical Sciences
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Study participating centre
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Sponsor information

Organisation
All India Institute of Medical Sciences

ROR
https://ror.org/02dwcqs71

Funder(s)

Funder type
University/education

Funder Name
All-India Institute of Medical Sciences

Alternative Name(s)
AIIMS

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
India

Results and Publications

Individual participant data (IPD) sharing plan
The dataset generated and/or analysed during the current study will be available upon request from Dr Gautam Sharma, drsharmagautam@aiims.edu.

The data generated during this study will be published as a supplement to the result publication after six months. Written consent forms will be obtained from each participant. Anonymized data will be a part of the published article.

IPD sharing plan summary

Available on request, Published as a supplement to the results publication