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The effect of mindfulness meditation on sleep quality and negative emotions in stroke patients with heart disease

Submission date
20/06/2024

Recruitment status
No longer recruiting

Registration date
24/06/2024

Overall study status
Completed

Last Edited
24/06/2024

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Sleep is one of the most fundamental and essential physiological needs for humans. It plays a crucial role in the recovery of the body, the integration and consolidation of memory, and is an indispensable component of health. Neuroscientific research indicates that sleep is a state required for maintaining highly physiological functions, adaptive behaviors, and biological defense mechanisms. Sleep significantly affects both physical and mental health, as well as the onset and progression of various diseases. Mindfulness meditation, as an emerging non-pharmacological therapy, has garnered considerable research attention in the field of insomnia in recent years and is considered an effective adjunctive method for improving sleep. This study aims to observe the effects of combining oral eszopiclone with mindfulness meditation on insomnia in stroke patients with concurrent coronary heart disease through a prospective randomized controlled clinical trial, in hopes of providing a more advantageous reference for rehabilitation treatment of such patients in clinical settings.

Who can participate?
Stroke patients with concurrent coronary heart disease whose sleep quality and negative emotions are currently affected

What does the study involve?
Participants will be randomly allocated to two groups that will receive routine treatment, including medication therapy and conventional rehabilitation training. Medication Therapy includes antiplatelet medication, lipid-lowering and plaque-stabilization medication, blood glucose control, blood pressure management, and neurotrophic medication. Conventional Rehabilitation Training: this is tailored according to the functional impairments of the patients and includes limb motor function training in stroke patients, activities of daily living (ADL) training, and related physical therapies.
For the control group, in addition to the standard treatment, eszopiclone tablets (Disha Pharmaceutical Group Co., Ltd., approval number H20213830, 3 mg/tablet) will be administered orally before bedtime, at a dosage of 3mg once daily.
In the intervention group, mindfulness meditation training is added to the treatment regimen

based on the control group's therapy. The intervention is divided into three stages, with the mindfulness meditation protocol developed according to relevant literature.

What are the possible benefits and risks of participating?
Mindfulness meditation can effectively improve sleep quality and reduce negative emotions in stroke patients with concurrent coronary heart disease, as well as promote the recovery of limb functions. There is little evidence about the potential harmful effects of mindfulness meditation. But caution is needed.

Where is the study run from?
The Second Hospital of Hebei Medical University

When is the study starting and how long is it expected to run for?
May 2021 to April 2024

Who is funding the study?
Health Commission of Hebei Province 2022 Hebei Province Medical Science Research Project

Who is the main contact?
Guangxiao Ni, kll51x6g4@163.com

Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
2022 Hebei Province Medical Science Research Project number: 20221008

Study information

Scientific Title
Efficacy of mindfulness meditation on sleep quality and negative emotions in stroke patients with concurrent coronary heart disease

Acronym
Effect of Mindfulness Meditation on Stroke Patient

Study objectives
To investigate the efficacy of mindfulness meditation on sleep quality and negative emotions in stroke patients with concurrent coronary heart disease.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 20/05/2021, Research Ethics Committee of The Second Hospital of Hebei Medical University (No. 215 Heping West Road, Xinhua District, Shijiazhuang City, 050051, China; +86 66002811; kll51x6g4@163.com), ref: 2021-R296

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Sleep quality and negative emotions in stroke patients with concurrent coronary heart disease

Interventions
Eligible stroke patients with concurrent coronary heart disease at the Second Hospital of Hebei Medical University will be selected. The patients will be randomly divided into an intervention

group and a control group. The control group will receive routine treatment plus eszopiclone tablets, while the intervention group will receive mindfulness meditation in addition to the treatment given to the control group.

Routine treatment included medication therapy and conventional rehabilitation training. Medication Therapy included: This included antiplatelet medication, lipid-lowering and plaque-stabilization medication, blood glucose control, blood pressure management, and neurotrophic medication. Conventional Rehabilitation Training: This was tailored according to the functional impairments of the patients and included limb motor function training in stroke patients, activities of daily living (ADL) training, and related physical therapies.

For the control group, in addition to the standard treatment, eszopiclone tablets (Disha Pharmaceutical Group Co., Ltd., approval number H20213830, 3 mg/tablet) were administered orally before bedtime, at a dosage of 3mg once daily.

In the observation group, mindfulness meditation training was added to the treatment regimen based on the control group's therapy. The intervention was divided into three stages, with the mindfulness meditation protocol developed according to relevant literature.
1. Introduction Stage (Week 1)
2. Maintenance Stage (Week 2)
3. Consolidation Stage (Weeks 3 to 6)
Participating patients were required to practice mindfulness meditation for 45 minutes each night before bed, record the time and their feelings after completing the practice, and continue this training for 6 weeks, with focused feedback and Q&A sessions in a WeChat group every Sunday. After 6 weeks of treatment, participants from both groups were to gradually reduce and then cease using eszopiclone within a maximum of 2 weeks.

Data will be collected before the intervention, and/or after 6 and 12 weeks of the intervention, including general information, Pittsburgh Sleep Quality Index (PSQI), Self-Rating Anxiety Scale (SAS) scores, Self-Rating Depression Scale (SDS) scores, and Fugl-Meyer Assessment (FMA) scores. Demographic data comprises gender, age, BMI, disease duration, education level, stroke location, stroke region, marital status, place of residence, limb disability, hypertension, diabetes, and per capita monthly income.

The PSQI will be used to assess the patient's sleep quality. The total score ranges from 0 to 21, with scores >7 indicating sleep disturbances. The higher the score, the poorer the sleep quality. The SDS and SAS were used to evaluate the visitor's depression and anxiety levels. An SDS score > 72 indicates severe depression; an SDS score of 63-72 suggests moderate depression; an SDS score of 53-62 indicates mild depression; an SDS score <53 signifies the absence of depression. A SAS score >69 denotes severe anxiety that requires immediate referral to a professional psychology institution; a SAS score of 60-69 indicates moderate anxiety, with the testee often feeling anxious recently, yet generally able to self-regulate; a SAS score of 50-59 suggests mild anxiety, with occasional anxious experiences recently, but with minor symptoms that usually quickly resolve after timely adjustment; a SAS score <50 signifies the absence of anxiety, considered a normal state. Motor function will be assessed using the FMA, including the Upper Limb Motor Function Assessment (comprising 33 items, with a total score of 66) and the Lower Limb Motor Function Assessment (comprising 17 items, with a total score of 34). A higher score indicates better motor function of the affected limb.

Intervention Type
Mixed

Primary outcome measure
The following primary outcome measures will be assessed before the intervention, and/or after 6 and 12 weeks of the intervention:
1. Sleep quality measured using the Pittsburgh Sleep Quality Index (PSQI)
2. Anxiety measured using the Self-Rating Anxiety Scale (SAS)
3. Depression measured using Self-Rating Depression Scale (SDS)
4. Motor function measured using the Fugl-Meyer Assessment (FMA)

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
05/05/2021

Completion date
30/04/2024

Eligibility

Key inclusion criteria
1. First onset of ischemic stroke confirmed via imaging, with a prior clear diagnosis of concurrent coronary heart disease
2. Presence of insomnia that appeared either after the stroke or within one month before the stroke onset, with a Pittsburgh Sleep Quality Index (PSQI) score of ≥ 7
3. Self-Rating Anxiety Scale (SAS) score of ≥ 50 and Self-Rating Depression Scale (SDS) score of ≥ 53
4. Clear consciousness, normal cognitive function, and ability to cooperate with treatment
5. Voluntary signing of informed consent by the patient and their family for participation in this trial

Participant type(s)
Patient

Age group
Mixed

Sex
Both

Target number of participants
72

Total final enrolment
72

Key exclusion criteria
1. Aphasia, abnormal mental behavior post-AIS, or severe consciousness disorders
2. Existence of unstable angina or myocardial infarction within the past two weeks
3. Significant organ dysfunction
4. Patients with malignant tumors

5. Existence of sleep disorders for more than one month before the stroke onset, or sleep disorders caused by medications or other systemic diseases
6. History of allergy to eszopiclone or similar medications

Date of first enrolment
01/05/2023

Date of final enrolment
20/04/2024

Locations

Countries of recruitment
China

Study participating centre
The Second Hospital of Hebei Medical University
No. 215 Heping West Road, Xinhua District
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Sponsor information

Organisation
Second Hospital of Hebei Medical University

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No. 215 Heping West Road, Xinhua District
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Sponsor type
Hospital/treatment centre

Website
http://www.hb2h.com/

ROR
https://ror.org/015ycqv20

Funder(s)

Funder type
Government

Funder Name
Health Commission of Hebei Province

Alternative Name(s)
Hebei Provincial Health Commission,

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
China

Results and Publications

Publication and dissemination plan
Planned publication in a peer-reviewed journal

Intention to publish date
31/01/2025

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study will be available upon request from Guangxiao Ni (kll51x6g4@163.com)

IPD sharing plan summary
Available on request