Patient Informed Consent

Project title: Mechanisms of the interaction between mood and sleep disorders	
Unit：Qilu Hospital, Shandong University	
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Co-host/Participant: None	Title:
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Informed Consent Version Number: V2.0	Informed Consent Version Date: 11 October 2024
Name of voluntary subject: ID number: Gender: Age: Correspondence address: Phone: Medical record number:	

We hereby invite you to participate in a medical research project, and this informed consent form provides you with information to help you decide whether or not to participate in this study. Please read the following carefully and discuss any questions or terms that are not clear with the study doctor.

Your participation in this study is completely voluntary and the project has been reviewed by the Research Ethics Committee of Qilu Hospital, Shandong University.

Background of the study: background significance (including domestic and foreign research progress) in easy-to-understand language

The effects of emotional states on sleep are mediated by a complex set of physiological and psychological processes. Studies have shown that mood disorders significantly affect autonomic function. In severely depressed patients and patients with concomitant anxiety, HRV is reduced, suggesting impairment of autonomic function in patients with mood disorders, and the parasympathetic nervous system is involved in regulating anxiety-related responses by influencing cardiac function through its neural activity. In addition, patients with various types of sleep disorders also experience autonomic dysfunction. For example, patients with chronic insomnia show enhanced sympathetic activity during sleep, especially during the rapid eye movement stage of sleep, whereas it is less pronounced during slow wave sleep. Obstructive sleep apnoea is associated with dysregulation of the sympathetic nervous system and sympathetic excitation. However, the mechanisms involved remain unclear. Although the association between mood and sleep disorders is widely recognised, research on the underlying mechanisms is still limited and it is difficult to develop effective intervention strategies accordingly. As an emerging biomonitoring method that can simultaneously monitor and analyse the activities of the brain and the heart, the Heart-Brain Synthesis (CBMS) method can help to elucidate the related physiological activities from a new perspective, provide evidence for determining the mechanism of the influence of emotions on sleep disorders, and improve the accuracy of diagnosis and assessment of the effectiveness of treatments. The heart-brain homoeostasis method plays a crucial role in revealing the complex connection between mood and sleep disorders, and is expected to improve our research on the mechanisms of mood and sleep disorders, and thus enhance the public's physical and mental health.

Purpose of the study:

We respectfully invite you to participate in a medical research programme with 150 patients and 50 healthy volunteers in China. This programme is based on previous research and will explore the mechanisms by which mood and sleep disorders interact with each other. The implementation of the study will help to further reveal the pathogenesis of sleep disorders and provide new clinical evidence for the optimal treatment of sleep disorders .

Your participation in this study will enable us to further explore the complex links between mood and sleep disorders and improve our research on the mechanisms of mood and sleep disorders.

Research Methods: (Including subject enrolment criteria and number of subjects; study design and conduct steps; study duration and progress;

Follow-up or rehabilitation programme; Evaluation and statistical methods.)

(1) Enrolment Criteria and Number of Subjects

Criteria for inclusion

(1) Normal Healthy Group

Inclusion Criteria:

Physical, mental, psychological, and social relationships are in perfect health.

Exclusion Criteria:

① Neurological and psychiatric diseases;

② History of sleep disorders;

③ history of other chronic or systemic diseases.

(2) Mood disorders with insomnia

Inclusion criteria:

① Meet the above diagnostic criteria for insomnia.

(ii) Age between 18 and 80 years old; (iii) PSQI＞5; and (iv) A history of other chronic or systemic diseases.

③ PSQI＞5, ISI＞7 , HAMA＞ 7 and/or HAMD≥ 7.

④ No communication barriers; ⑤ Sign the informed consent form.

⑤ Signed informed consent.

Exclusion Criteria

(i) Secondary insomnia caused by other physical diseases; (ii) Other types of sleep disorders and mood disorders.

Other types of sleep disorders and mood disorders.

③Environmental or other human factors disturbing sleep for a long time.

(3) Mood disorder without insomnia group

Inclusion Criteria

(1) Does not meet the above diagnostic criteria for insomnia ;)

(ii) The age is 18 to 80 years old.

③ PSQI≤ 5, ISI≤ 7, HAMA>7 and/or HAMD≥ 7; ④ No communication disorders; and

④No communication barriers; ⑤Sign the informed consent form.

⑤ Signed informed consent.

Exclusion criteria.

(i) Presence of insomnia and other sleep disorders

(4) Primary insomnia

Inclusion Criteria

① meets the above diagnostic criteria for insomnia; ② does not meet the above diagnostic criteria for mood disorders; ③ does not meet the above diagnostic criteria for mood disorders

(ii) Do not meet the above diagnostic criteria for mood disorders.

(iii) The age is 18 to 80 years old.

④ PSQI＞5, ISI＞7, HAMA≤ 7 and HAMD＜7.

⑤ No communication barriers;

⑥ Signed informed consent.

Exclusion criteria:

① secondary insomnia caused by other somatic diseases; ② secondary insomnia caused by other somatic diseases; ③ secondary insomnia caused by other somatic diseases.

Other types of sleep disorders were excluded.

③Environmental or other human factors disturbing sleep for a long time.

PASS software was applied to determine sleep improvement based on PSG sleep data, PSQI score and ISI score. 50 cases of mood disorders with insomnia group, 50 cases of mood disorders without insomnia group, 50 cases of primary insomnia group, and 50 cases of normal healthy group were included according to the literature.

(2) Study design and main steps

All enrollees signed an informed consent form

(1) Measurement of variables before the start of the experiment

Including general clinical information, scale assessment, and ambulatory electrocardiogram (10KB/copy). Scale assessment included: measurement of Pittsburgh Sleep Quality Index (PSQI) (description: 0-5 very good, 6-10 okay, 11-15 fair, 16-21 very poor), Insomnia Severity Index (ISI) (description: total score range: 0-28,0-7 no clinically significant insomnia, 8-14 subthreshold insomnia, 15-21 clinically insomnia moderate-severe, 22- 28 clinically significant insomnia), Montreal Cognitive Assessment Scale (MoCA) (description≥ 26 points normal), Brief Mental State Examination (MMSE) (description:≥ 27 points normal,

21-26 mild, 12-20 moderate, <12 severe), Hamilton Anxiety Scale (HAMA) (description:≥ probably severely anxious,≥ 21 points definitely significantly anxious,≥ 14 points definitely anxious, >7 possibly anxious,≤ 7 normal), Hamilton Depression Scale (HAMD) (description: <7 no depression, 7-12 mild depression, 18-24 moderate depression, >24 severe depression), Epworth Sleepiness Scale (ESS), SF-36 Quality of Life Scale, and other relevant scale information. A simplified formula was used to estimate basal metabolic rate, e.g., Gale's formula: % basal metabolic rate = (pulse rate + pulse pressure) - 111.

(2) Variables were measured while the experiment was in progress:

0 minutes to 30 minutes after the lights were switched off Measurements The following data were taken

POMS scale of state of mind and blood pressure and basal metabolic rate, EEG were measured 0 min before the start of the experiment.

ECG/magnetic and EEG/magnetic monitoring: sympathetic nervous system activity. (full 30 minutes)

- Statistical Analysis.

Specific material to be collected for the study:

Data collection for all enrolled subjects will include: information from the subject's medical record including general clinical information, scale assessment, blood pressure, ambulatory electrocardiogram, electroencephalogram, and basal metabolic rate. Electrocardiographic/magnetic and electroencephalographic/magnetic monitoring: sympathetic nervous system activity. (Full 30 minutes)

Cost of Participation in the Study Description:

There is no fee to participate in the study and all items involved in the study are free of charge.

Subject Compensation: none

Potential Benefits of Participating in the Study:

Subjects participating in this study will receive necessary medical care from the research team.

possible side effects and risks:

This study does not interfere with the subject's normal medical regimen and no biological samples are collected from the subject.

Other Possible Current Therapies and Their Descriptions:

None
Your Rights and Responsibilities: Participation in this clinical research study protects your personal rights under the following conditions: The investigator will be liable for damages in the event of injury arising out of the execution of the study protocol. 1. The organising body of this clinical research study will protect your rights and interests during the course of the study. 2. Your Privacy (1) Your medical records will be kept confidential by the research physicians and staff. Data collected, test results and physician's diagnosis will be kept confidential, and a code will be assigned to protect your name from disclosure. A code will be assigned to protect your name from disclosure. Your privacy will be maintained, except in the event of a legal investigation by the relevant authorities. (2) The data obtained from the study may be published for academic purposes, but your privacy (e.g. name, medical record number...) will not be released. (e.g. name, medical record number, etc.) will not be published and will be kept strictly confidential. 3. 3. You may keep yourself informed of the information and progress of this study. If you are harmed or have any questions about your rights during the study, please contact Haiyun Li at 18560088921. You have the right to refuse to participate in the study without giving any reason, and you may withdraw your consent at any time without causing any

discomfort or affecting your future medical care.

Informed Consent Signature Page

I have read the above information in detail, and any questions about the clinical research programme have been explained in detail by the research coordinator. I understand the status of the whole experiment and after due consideration, I agree to be a voluntary participant in this clinical research.

Signature of Voluntary Recipient:

Legal Representative: Relationship to the subject:

ID Number: Phone:

See Certificate Person: Relationship to Subject: ID No.: Phone No.: Phone No.

ID number: Phone number.

Date:

Investigator's Statement:

I confirm that the nature, purpose, requirements and possible risks of this study have been explained and discussed with the patient, and that alternative treatment options have been explored at the same time, and that I will inform the subject or his/her authorised representative promptly of any changes in the risk-benefit profile of the study during the course of the study.

Signature of the investigator: Month of the year