Research on the Mechanisms of the Interaction between Emotions and Sleep Disorders

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Summary of research program

Project Title	Research on the mechanism of the interaction between mood and sleep disorders
Purpose of Research	Primary purpose: To explore the mechanisms by which mood and sleep disorders interact. Exploratory Aims: 1. Discover the correlation between ECG/cardio-magnetic and EEG/Encephalomagnetic features and mood and sleep disorders; 2. correlation of mind-brain monitoring to explore mood and sleep disorders interactions.
Research hypotheses	1. Intrinsic mapping mechanism between mood and sleep disorders. 2. Possible reasons for the interaction between mood conduction and sleep disorders.
Study design	□ Case-control study □ Cohort study □ √ Cross-sectional study
Subjects	Criteria (1) Normal healthy group Inclusion Criteria: Physical, mental, psychological, and social relationships in a completely good state. 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: ② (a) Meet the above diagnostic criteria for insomnia. ② Age 18～ 80 years old.

③ PSQI＞ 5, ISI 7＞ , HAMA 7＞ and/or HAMD⩾ 7; and

④ No communication barriers; and

⑤ Signed informed consent.

Exclusion Criteria

(i) Secondary insomnia caused by other somatic 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) Do not meet the above diagnostic criteria for insomnia ;)

② Age is 18～ 80 years old.

③ PSQI⩽ 5, ISI⩽ 7, HAMA＞ 7 and/or HAMD ⩾ 7; and

④ No communication barriers; and

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 diagnostic criteria for mood disorders

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

③ Age 18～ 80 years old; ④ PSQI 5 years old.

④ PSQI＞ 5, ISI＞ 7, HAMA⩽ 7 and HAMD＜

	7; and ⑤ No communication barriers; ⑥ Signed informed consent. Exclusion criteria: ① secondary insomnia caused by other somatic diseases; ② other types of sleep disorders were excluded. ② Excluding other types of sleep disorders. ③ Environmental or other human factors interfere with sleep for a long time. 1.3 Experimental grouping: the study is divided into four groups, namely: normal health group; mood disorder with insomnia group; mood disorder without insomnia group; primary insomnia without mood disorder group.
Diagnostic criteria	The diagnostic criteria of insomnia were met: Patients were screened by two neurologists with -15 years of experience using a semi-standardized psychiatric and sleep related interview according to the Diagnostic and Statistical Manual of Mental Disorders, 5th edition (DSM- V) criteria . The selected subjects met the following criteria: ① Self-reported difficulty falling asleep, difficulty maintaining sleep, or early awakening; ② symptoms at least three times per week and for 3 months; ③ Concomitant with at least one associated impairment in daytime functioning (e.g., fatigue, mood disturbance, or cognitive impairment); ④ No other sleep disorder (e.g., obstructive sleep apnea or sleep-related movement disorders), serious organic disease, or psychiatric illness, such as depression

	or generalized anxiety; ⑤ All patients selected were not taking any psychoactive drugs for at least 2 weeks before and during the study period to eliminate drug effects;
Sample size and calculation basis	PASS software was applied to determine sleep improvement based on PSG sleep data, PSQI scores and ISI scores, and 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 reports
Main exposure factors	Includes general clinical information, scale assessments, ambulatory electrocardiograms, and electrocardiographic/magnetic and electroencephalographic/magnetic monitoring data. (100KB/copy)
Endpoint Variables	Primary endpoint: there is an intrinsic mapping and interaction between mood and sleep disorders. Secondary endpoints: 1. to reveal the manifestation of mind-brain interactions in emotions and their changes in sleep disordered states using simultaneous measurements of heart-brain electro/magnetic signals. Provide information about the spatiotemporal properties of mind-brain interactions, synchronization, and responses to external stimuli and internal regulation. 2. It is expected to obtain a complex mapping relationship between mood-mind-brain-sleep quality, to discover the mechanism by which mood and sleep disorders influence each other, and to provide new perspectives for understanding the interactions between

	mood disorders and sleep disorders.
Follow-up plan (To be completed for cohort study)	None
Sample collection	□ No☑ Yes Brief description of type of organization, volume Include general clinical information, scale assessment, blood pressure, ambulatory ECG, EEG, basal metabolic rate. ECG/MAG & EEG/MAG monitoring: sympathetic nervous system activity. (Full 30 minutes) (100KB/sample)
Screening for Non-Medical Purposes	☑ No □ Yes **e.g. non-essential CT, imaging, laboratory tests, etc.**
Statistical methods	For continuous variables, statistical descriptions were made using mean ± standard deviation, and for categorical variables, frequency and rate (%). For comparison of parameters between two groups, t-test or rank-sum test was used for continuous variables and chi-square test for categorical variables. For one-way correlation analysis, Pearson or Spearman correlation analysis was used. For multifactor analysis, generalized linear model or logistic regression model was used. All of the above parameters were considered statistically significant at $p<0.05$
Study risk self-assessment	□ High risk studies □ Medium risk studies ☑ Low risk studies Brief description: This study is a low-risk study, the research process, fully protect the patient's right to privacy and informed consent, the data obtained from the study can be published for academic needs, but the patient's privacy (such as

	name, medical record number, etc.) will not be published to absolute confidentiality, the patient before participating in the experiment are signed informed consent, and have the right to terminate participation in the study at any time.

Confidentiality Statement:

The information contained in this study protocol will be made available for review only by the investigator(s) of this project, the Clinical Research Management Committee, and the appropriate agencies. It is strictly forbidden to communicate any information to third parties not related to this study without the approval of the principal investigator.

1. Background of the study (state the basis and significance of the study in the light of the current state of internal and external research)

1. Rationale for the establishment of the project

(I) Significance of the study

Sleep is vital to human beings, and sleep can promote brain development , help consolidate memory, enhance human immunity and so on. About one-third of life is spent in sleep. In recent years, the incidence of sleep disorders, especially insomnia, has been on the rise. The 2024 White Paper on Sleep Health of Chinese Residents shows that 59% of people in China suffer from insomnia. Insomnia will directly lead to the patient's daytime function damage, such as daytime drowsiness, inattention, etc.[1] , affecting people's normal work life, and even for the traffic and other safety hazards. And insomnia is related to the dysfunction of cardiovascular and cerebrovascular system, endocrine system and digestive and respiratory system, etc., and plays a vital role in the development of chronic diseases, so insomnia has become an increasingly serious medical and social problems.

Meanwhile, with the development of society, the incidence of mental diseases is gradually rising. China's mental health survey shows that the prevalence of anxiety disorders in China is 4.98%, and the lifetime prevalence of depression is 6.9%[2] , Mood disorders can greatly affect the quality of life, and even seriously jeopardize people's physical health and life safety. Insomnia and mood disorders have a close relationship. Insomnia not only increases the risk of depression[3] , but also raises the risk of suicide[4] among young patients. In addition, mood disorders are also closely related to insomnia, anxiety and depression and other mood disorders will also increase the incidence of insomnia[5] , and some studies have shown that the quality of life of patients with major depression is related to insomnia[6] .

The effects of emotional states on sleep are multidimensional.Meneo et al. summarized multiple mechanisms by which emotions affect sleep, such as dysfunctions in the prefrontal cortex and amygdala, among others, as well as cognitive-behavioral factors. Among these mechanisms, dysfunction of the Autonomic Nervous System (ANS) is considered to be a central link[7] . The Autonomic Nervous System (ANS) is mainly composed of two major branches, the sympathetic and parasympathetic. On the one hand, under emotional stress or anxiety, the activity of the Sympathetic Nervous System (SNS) is enhanced, leading to physiological responses such as increased heart rate and blood pressure, which increases alertness and reduces the tendency to sleep[8] . On the other hand, during sleep, the activity of the Parasympathetic Nervous System (PNS) is enhanced, particularly through an increase in the high-frequency component of Heart Rate Variability (HRV), which contributes to the depth and quality of sleep[9] .

Although the association between mood and sleep disorders is widely recognized, 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 analyze the activities of the brain and heart and interpret the connection of the heart-brain axis from a new perspective, mind-brain homoeostasis can help to elucidate the related physiological activities, provide evidence for determining the mechanism of the influence of emotions on sleep disorders, and improve the accuracy of diagnosis and the evaluation of the effectiveness of treatments. The heart-brain synesthesia method plays a crucial role in revealing the complex connection between mood and sleep disorders, and is expected to improve our research on the mechanism of mood and sleep disorders and find new ways of intervention, thus enhancing the public's physical and mental health.

(II) Current status of domestic and international research

The effects of emotional states on sleep are mediated by a series of complex 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[8] , while the parasympathetic nervous system, through its neural activity, influences cardiac function and participates in the regulation of anxiety-related responses[10] . 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, while it is less pronounced during slow wave sleep[11] . Obstructive sleep apnea is associated with dysregulation of the sympathetic nervous system and sympathetic excitation[12] . However, the mechanisms involved remain unclear.

There are several ways to measure autonomic activity in mood disorders or sleep disorders. For example, classical HRV reflects the function and interconnection of sympathetic and parasympathetic nerves[13] . In addition, other measures such as plasma norepinephrine and cortisol levels, muscle sympathetic activity, changes in blood pressure, body temperature and basal metabolic rate, and sympathetic skin responses can also reflect autonomic function[12] . Although these methods of assessing sympathetic nervous system function provide different perspectives on sympathetic activity, they are unable to accurately differentiate between systemic and localized differences in sympathetic activity, and they are subject to the interference of a variety of physiological and environmental factors, which in turn affects the stability and accuracy of the assessment.

With the rapid development of quantum information technology, atomic magnetometer technology based on the SERF (Spin-Exchange Relaxation-Free) effect has made a breakthrough in the field of sensing biological weak electrophysiological signals[14] . Magnetic cardiography (MCG) technology utilizes highly sensitive multi-channel atomic magnetometer arrays to non-destructively and non-invasively record the weak magnetic field signals generated by myocardial electrical activity during the cardiac cycle, providing a new way to assist in the diagnosis of cardiovascular diseases, especially ischemic heart disease[15] . Compared with electrocardiography (ECG), magnetoencephalography (MEG) is free of interference from human tissues and can capture the weak magnetic field signals generated by the electrical activity of the heart more acutely, providing richer information[16] . Magnetoencephalography (MEG) is a technique that can measure neural activity in the brain with high temporal and spatial resolution by detecting the biomagnetic field formed by the weak currents generated by the excitatory postsynaptic potentials of neurons[17] . MEG technology has been used in many clinical studies for brain disorders such as Parkinson's disease, Alzheimer's disease, and autism to search for brain magnetic biomarkers[18-20] . These heart-brain magnetic imaging techniques based on ultra-high sensitivity and very weak magnetic field sensing provide new non-invasive and high-resolution means for the diagnosis and research of heart-brain diseases, and have important clinical application value and research potential.

Based on the development of heart and brain measurement technology, heart-brain synesthesia has shown its unique advantages in the field of mood and sleep. The University of Konstanz has revealed the role of heart-brain signal measurements in understanding emotional responses by analyzing the effects of emotional images on magnetoencephalography and heart rate[21] , and Japanese scholars' research on the moderating effect of fasting on physiological-psychological responses to emotional pictures[22] . For sleep research, Beijing Institute of Technology proposed a sleep quality assessment method based on the combination of EEG and ECG multimodal features[23] in 2023 , which not only improves the accuracy of sleep disorder diagnosis, but also provides strong support for clinical diagnosis and treatment. Combining EEG and ECG, the study also demonstrated that the sympathetic-parasympathetic activity of the heart plays an initiating role in the process of emotional arousal, and that there is a causal relationship between this activity and brain dynamics[24] . Heart-brain co-testing can synchronize the recording of cardiac dynamics and the activation of brain structures, providing the underlying mechanisms related to the activity of the heart-brain axis and, accordingly, providing effective interventions and efficacy assessment methods. The development of cardio-cerebral homoeostasis provides new perspectives and methods for the study of physical and mental health, and opens up a new path for the diagnosis and treatment of sleep disorders.

2. Research Problems, Research Objectives (Elaborate the scientific problems and research objectives of the study)

2.1 Research question:

Intrinsic mapping mechanism between heart-brain electrical/magnetic features and other features and emotions and sleep disorders: to reveal the manifestation of heart-brain interactions in different emotions and the changes in sleep disordered states. To study the intrinsic mapping mechanism between mind-brain electrical/magnetic features and mood and sleep disorders, to extract the mind-brain electrical/magnetic features associated with sleep disorders, and to study the possible reasons for the interaction between mood and sleep disorders.

2.2 Primary research objective: Primary objective: to explore the mechanism of the interaction between mood and sleep disorders.

2.3 Secondary and exploratory research aims:

Exploratory Aims: 1. to discover the relationship between ECG/cardio-magnetic and EEG/Encephalomagnetic characteristics and mood and sleep disorders;

2. correlation of mind-brain monitoring to explore mood and sleep disorders interacting with each other.

3. research methodology (this section is the focus of the presentation)

3.1 Research Design

3.1.1 Research methodology through cross-sectional studies

3.1.2 General information collection: detailed baseline data were collected from all participants, including basic demographic characteristics such as age, gender, education level, health status, sleep and lifestyle.

3.1.3 Prior to the start of the experiment, the Pittsburgh Sleep Quality Index (PSQI), Insomnia Severity Index (ISI), Montreal Cognitive Assessment Scale (MoCA), Brief Intelligence Mental State Examination (MMSE), Hamilton Anxiety Scale (HAMA), Hamilton Depression Scale (HAMD), Epworth Sleepiness Scale (ESS), SF-36 Quality of Life Scale (QOLS) and other relevant scale information and dynamic electrocardiogram.

3.1.4 Measurement of POMS scale and blood pressure and basal metabolic rate, EEG 0 minutes before the start of the experiment.

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

3.2 Study site and study population (source and inclusion exclusion criteria)

3.2.1 Data collection: all data in this study were obtained from outpatients and inpatients/healthy volunteers of Qilu Hospital of Shandong University.

3.2.2 Diagnostic and Inclusion and Exclusion Criteria of Study Subjects:

Insomnia diagnostic criteria:

Patients were screened according to Diagnostic and Statistical Manual of Mental Disorders, 5th edition (DSM-V) criteria by two neurologists with 15 years of experience using a semi-standardized psychiatric and sleep-related interview. The selected subjects met the following criteria:

① Self-reported difficulty falling asleep, difficulty maintaining sleep, or early awakening;

(ii) Symptoms were present at least three times per week and had persisted for 3 months;

(iii) Concomitant with at least one associated impairment in daytime functioning (e.g., fatigue, mood disorders, or cognitive impairment);

④ No other sleep disorders (e.g., obstructive sleep apnea or sleep-related movement disorders), serious organic diseases, or psychiatric disorders, such as depression, generalized anxiety;

⑤ All patients selected were not taking any psychoactive drugs for at least 2 weeks before and during the study to eliminate drug effects;

NAC criteria

(1) Normal healthy group

Inclusion criteria:

Physical, mental, psychological, and social relationships in a completely good state.

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.

② Age 18～ 80 years old; ③ PSQI 5.

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

④ No communication barriers; and

⑤ Signed informed consent.

Exclusion Criteria

① Secondary insomnia caused by other somatic diseases; ② 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) Do not meet the above diagnostic criteria of insomnia; (2) Aged 18 80 years old.

② Age is 18～ 80 years old.

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

④ No communication barriers; and

⑤ Signed informed consent.

Exclusion criteria.

(i) Presence of insomnia and other sleep disorders

(4) Primary insomnia

Inclusion Criteria

① Meet the above diagnostic criteria for insomnia.

①Does not meet the above diagnostic criteria for mood disorders.

③ Age 18～ 80 years old.

④ PSQI＞ 5, ISI＞ 7, HAMA≤ 7 and HAMD＜ 7; and

⑤ No communication barriers;

⑥ Signed informed consent.

Exclusion criteria:

① secondary insomnia caused by other somatic diseases; ② other types of sleep disorders were excluded.

② Excluding other types of sleep disorders.

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

3.3 Study Variables (Factors) and Measurement

(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 normal), Brief Mental State Examination (MMSE) (description: ⩾27 normal, 21-26 mild, 12-20 moderate, <12 severe), Hamilton Anxiety Scale (HAMA) (description: ⩾probably severe anxiety, ⩾21 definitely significant anxiety, and ⩾14 definitely anxious, >7 probably 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 related scale information. Simplified formulas were used to estimate basal metabolic rate, such as the Gale formula: basal metabolic rate % = (pulse rate + pulse pressure)-111.

(2) Measurement of variables while the experiment was in progress:

0 minutes to 30 minutes after the lights were turned off Measurements The following data (100 KB/copy)

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

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

3.4 Study Outcomes

3.4.1 Primary outcome variable: there is an intrinsic mapping and interaction between mood and sleep disorders.

3.4.2 Secondary outcome variables:

1. Using simultaneous measurements of mind-brain electrical/magnetic signals, reveal how mind-brain interactions manifest themselves in emotions and how they change in sleep-disordered states. Provide information about the spatiotemporal properties of mind-brain interactions, synchronization, and response to external stimuli and internal regulation.

2. It is expected to obtain a complex mapping relationship between mood-mind-brain-sleep quality, to discover the mechanism by which mood and sleep disorders influence each other, and to provide new perspectives for understanding the interactions between mood disorders and sleep disorders.

3.5 Follow-up (to be filled in by cohort study)

3.6 Sample size

Applying PASS software, sleep improvement was determined based on PSG sleep data, PSQI score and ISI score, and 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 reports

3.7 Data collection and management

Data collection was firstly collected by applying the paper version of the case report form, and the subjects' information (including general clinical data, scale assessment, blood pressure, dynamic ECG, EEG, basal metabolic rate) was then entered into the computer by specialized personnel. ECG/ECG and EEG/MEG data were measured by specialized personnel. Statistical analysis was performed by a clinical statistician.

3.8 Statistical Analysis Methods

For continuous variables, statistical descriptions were performed using mean ± standard deviation, and for categorical variables, frequency and rate (%). For comparison of parameters between two groups, t-test or rank sum test was used for continuous variables and chi-square test was used for categorical variables. For one-way correlation analysis, Pearson or Spearman correlation analysis was used. For multifactor analysis, generalized linear model or logistic regression model was used. All of the above parameters were considered statistically significant at $p<0.05$

Quality control

1) Clinical data disease diagnosis: determined by two chief physicians of sleep disorder group;

2) Scale assessment: determination by two scale-trained neurologists;

(3) Sleep apnea monitoring: determination by two specialized PSG charting physicians;

(4) Ambulatory electrocardiogram (ECG): performed by two specialized physicians specializing in the interpretation of ambulatory electrocardiograms;

(5) Electroencephalogram (EEG): determination by two specialized EEG interpreting doctors;

6) ECG/magnetic and EEG/magnetic monitoring: determination by two specialized

professionals;

7) Statistics: performed by clinical statisticians;

4. Research feasibility analysis

4.1 Theoretical feasibility

This topic is well-founded, reasonably designed and operable: the group has referred to a large amount of literature, the topic is reasonably designed, the technical route is correct, and the source of the required samples is sufficient; the group has been engaged in the research related to the pathogenesis and treatment of sleep disorders and mood disorders for a long time, and it has a good foundation for the work.

4.2 Feasibility of methodology and personnel

The research group has a reasonable composition of personnel with rich research experience, a reasonable mix and a clear division of labor, which can ensure the smooth completion of all steps in this project. The clinical scales and related indexes required for this study have been widely used in medical research, and the technology is mature and reliable; the number of patients with mood disorders and sleep disorders in Qilu Hospital of Shandong University is large, and there is a base of sample size. The R&D team has many years of R&D experience in ultra-high sensitivity weak magnetic field measurement, and has developed two generations of ultra-high sensitivity magnetic field and inertia measurement experimental devices since 2013 with the support of the National Natural Fund Committee of China. Based on the above technology foundation, the team has independently innovated and developed a weak cardiac magnetic imaging device and a weak brain magnetic measurement device, which are close to the best international level, and offer transformative new technologies for cardiac disease research, neuroscience, and brain science. The team has provided transformative new technologies for heart disease research, neuroscience and brain science. The project leader has been deeply engaged in psychosomatic and sleep disorders for a long time. He is the young vice-chairman of the Chinese Medical Association's Psychosomatic Medicine Branch and the vice-chairman of the Shandong Provincial Medical Association's Geriatrics Society, and he is in charge of the Shandong Provincial Key Research and Development Program "Caring for You and Me, Caring for Others", the National Mental Health Project, and he has carried out the sleep clinic and polysomnography. As the main researcher, he has undertaken a number of clinical trials on psychosomatic and sleep disorders, and has conducted a number of clinical and scientific studies on psychosomatic disorders and sleep disorders.

5. Time plan

Annual arrangement of the research program and expected research results

2024.10-2026.02 Screening of enrolled subjects, completion of baseline assessment, measurement of cardiac/magnetic and cerebral/electromagnetic and related auxiliary examination indexes;

2026.03-2027.02 Collect data and group samples for the period;

2027.03-2027.10 Data analysis and writing of the article.

6. References

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