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Author(s): Shan Zhou, Xinyu Liu, Zhenzhen Ru, Mengyuan Liu, Jiabin Tai, Liwei Guo, Jiang Tan, Jing Hu, Ning Qiang, Junming An, Feilong Feng, Jin Li

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Study on the Novel Hyperbolic Acoustic-focusing Transducer by Stimulating the Auricular Acupoints for Improving Sleep Disorder

Shan Zhou^{1†}, Xinyu Liu^{1†}, Zhenzhen Ru¹, Mengyuan Liu¹, Jiaxin Tai¹, Liwei Guo¹, Jiang Tan¹, Jing Hu¹, Ning Qiang¹, Junming An^{2,*}, Feilong Feng^{1,*}, Jin Li^{1,*}

¹ Shaanxi Provincial Key Laboratory of Ultrasonics, Shaanxi Normal University, Xi'an 710119, China

² Xi'an Hospital of Traditional Chinese Medicine, Department of Acupuncture, Tuina and Rehabilitation

†Shan Zhou and Xinyu Liu share first authorship and contributed equally to this work.

*Corresponding Author email: an_71@163.com (Junming An), fengfeilong@snnu.edu.cn (Feilong Feng), lijn1997@snnu.edu.cn (Jin Li)

Abstract

Modulating the body through peripheral stimulation is an effective approach for treating sleep disorder. This study aims to design a novel hyperbolic acoustic-focusing transducer using low-intensity focused ultrasound (LIFU) technology for stimulating the auricular acupoints to improve sleep disorder. First, the key radiation parameters for hyperbolic acoustic-focusing transducer (such as acoustic stimulation intensity, transmission frequency and dimensions) were determined through COMSOL Multiphysics 6.2 simulations. Then, the external acoustic field of the hyperbolic acoustic-focusing transducer was measured through hydrophone experiments, which fully verified the validity of the parameters. Finally, 80 patients with sleep disorder were enrolled in the clinical trial. During the trial, electrocardiogram (ECG) data were collected. Sleep quality was assessed using ECG signal analysis and questionnaire analysis. Key acoustic stimulation intensity parameters were set as follows: 1 MHz frequency, 20%-50% duty cycle, 30 kPa acoustic pressure, 5 minutes radiation duration, 1.5 mm acoustic output end radius, 2.5 mm acoustic input end radius, and 4 mm length. The hyperbolic acoustic-focusing transducer can generate a stable needle focal spot, ensuring accurate stimulation of auricular acupoints. Questionnaire assessment indicators, such as the Pittsburgh Sleep Quality Index (PSQI), were significantly lower than before treatment. ECG signal analysis showed that the average nightly sleep duration increased from 4.04 hours to 6.82 hours. Ultrasound stimulation of auricular acupoints significantly prolongs sleep duration, improves sleep quality and regulates emotional state in patients.

Keywords: Hyperbolic acoustic-focusing transducer; Needle focal spot; Low-intensity focused ultrasound technology; Radiation parameters; Sleep disorder.

1. Introduction

Acupuncture is a promising non-pharmacological therapy for various diseases(Kim et al., 2025). Numerous epidemiological studies have shown that the prevalence of sleep disorder increases with age(Alanazi et al., 2025; Lin et al., 2025), leading to a growing demand for convenient and personalized treatment. The convenient home-based devices have emerged in response to this demand. Compared with traditional devices, these devices feature lower cost and simpler operation, enabling daily treatment management through wearable or handheld designs(Song et al., 2024). Modern acupuncture-like stimulation technologies (including electrical, magnetic, laser, and ultrasound stimulation) have the advantages of easily quantifiable parameters and low reliance on operator skills, making them highly suitable for the development of home-based therapeutic devices(Krone et al., 2025; Cai et al., 2025). However, in practical applications, laser stimulation has limited penetration depth, while electrical and magnetic stimulation rapidly attenuate in tissues(Li et al., 2024). In contrast, ultrasound technology exhibits great medical potential due to its high spatial resolution and deep penetration capability(Dell'Italia et al., 2022; Bawiec et al., 2025; Zhong et al., 2024).

Sleep disorder has become a serious public health problem(Liu, Li, 2025). In particular, sleep disorder is also associated with various other physical and mental illnesses(van Straten et al., 2025). Therefore, timely and effective treatment for sleep disorder is urgently needed(Liu et al., 2025). Long-term pharmacotherapy may pose risks such as drowsiness, drug dependence, and cognitive and behavioral changes. Acupuncture, as a therapy of Traditional Chinese Medicine (TCM), is widely used to treat sleep disorders(Zhang et al., 2022a; Zhang et al., 2022b; Lu et al., 2022). However, acupuncture for the treatment of sleep disorders has several challenges, including a large patient volume, long treatment courses, and heavy reliance on clinicians' clinical operations. Integrating ultrasound technology with acupuncture therapy to develop a convenient home-based device is a promising approach to overcoming current challenges.

Ultrasound is a noninvasive mechanical wave that can exert thermal and mechanical effects on tissues and can be used for noninvasive medical interventions(O'Reilly, 2024). Low-intensity focused ultrasound (LIFU) is a non-invasive therapeutic modality(Wang et al., 2025). It delivers mechanical energy to target tissues by focusing acoustic energy on them. LIFU represents a

groundbreaking medical advancement, characterized by non-invasiveness, safety, precision, and extensive neuromodulatory capabilities(Feng, Li, 2024). Studies have shown that ultrasound can modulate neuronal activity and promote neuronal growth, repair, and functional recovery(Li et al., 2025). Ultrasonic acupuncture exerts thermal and mechanical stimulation at local acupoints, inducing deqi sensations throughout the body, and can fully replace traditional acupuncture(Xia et al., 2026).

Auricular acupoints, as representative therapeutic acupoints in TCM. The entire auricular acupoint region forms a complex and delicate neurovascular network that connects to the central nervous system (CNS). Auricular acupoint stimulation technology has demonstrated significant therapeutic efficacy in patients with insomnia. However, in terms of operational methods, acupuncture can cause excessive stimulation of the cartilage and is prone to infection of the auricle(Guo et al., 2024). In clinical practice, auricular acupoints are often stimulated not with needles, but with auricular beans. However, this method relies on doctors for application and requires patients to apply manual pressure, making it unsuitable for home use. Consequently, new stimulation technologies (such as ultrasound) are urgently needed.

In recent years, ultrasound stimulation at various frequencies, pulse widths, and acoustic pressures has been applied to various animals and humans(Dell'Italia et al., 2022), verifying the effectiveness of focused ultrasound for non-invasive neuromodulation(Collins, Mesce, 2022; Lee et al., 2024). Human acupoint tissue features a "skin-fat-bone" three-layer interface structure, and tissue thickness varies among different acupoints(Lee et al., 2024). If the single-element focused transducer is used, it must be replaced when the focal depth needs to be adjusted, which is not conducive to practical application. Although the concentric multi-element ring transducer can achieve dynamic focusing of sound waves, it has a trade-off between focal length and focal beam width: the greater the focal length, the lower the axial resolution(Collins, Mesce, 2022). Therefore, the novel acoustic-focusing transducer is urgently needed.

In this study, the novel hyperbolic acoustic-focusing transducer was designed to improve sleep disorder through ultrasonic stimulation of auricular acupoints. The key radiation parameters of this transducer were determined through COMSOL Multiphysics 6.2 simulations and hydrophone experiments. The clinical trials were conducted using this transducer to stimulate auricular acupoints of patients with sleep disorder. The efficacy of improving sleep disorder is verified through ECG signal analysis and questionnaire analysis.

2. Materials and Methods

2.1. Parameter Settings

2.1.1. Acoustic Stimulation Intensity Selection

As a key parameter in the design of the hyperbolic acoustic-focusing transducer, the acoustic stimulation intensity must meet safety and energy transmission stability requirements. In the field of medical ultrasound, acoustic stimulation intensity must be strictly limited within the physiological tolerance range of biological tissues to avoid organic damage from excessive energy input. To scientifically determine the reasonable value ranges of acoustic stimulation intensity parameters. This study recruited 20 healthy volunteers of different ages and genders to conduct a special experiment on the acoustic stimulation tolerance of auricular acupoints.

The acoustic stimulation intensity parameters were determined as follows: duty cycle of 20%–50%, excitation acoustic pressure of 30 kPa, and radiation duration of 5 min, based on the results of this tolerance test.

2.1.2. Frequency Selection

The "Pressure Acoustics, Frequency Domain" module (referenced from the COMSOL Application Gallery example "Propagation of High-Intensity Focused Ultrasound (HIFU) in a Tissue-Mimicking Phantom") was selected using COMSOL Multiphysics 6.2. As shown in Fig. 1a, the ultrasound stimulation region was configured as water, and the boundary was configured as a perfectly matched layer (PML) (2 mm-thick) to fully absorb the acoustic waves propagating to this interface. The hollow inner cavity of the hyperbolic acoustic-focusing transducer should be filled with an acoustic coupling medium to achieve efficient transmission of acoustic energy. Polyacrylamide (PAA) hydrogel is selected in this study. It exhibits an acoustic attenuation of 0.08–0.14 dB/cm and an acoustic impedance of 1.58–1.68 MRayl at 1 MHz. Its acoustic impedance matches well with human soft tissue (~1.63 MRayl). The interfacial reflection can be neglected (Prokop et al., 2003). Among four candidate materials including agar, silicone, PVA and PAA, PAA delivers the best comprehensive performance with respect to impedance matching and formability (Zell et al., 2007). Aluminum alloy is adopted as the hyperbolic outer shell material. The acoustic impedance of aluminum alloy (~17 MRayl) differs substantially from that of the internal medium (~1.5 MRayl). Acoustic waves experience near-total reflection at the wall interface, confining acoustic energy within the cavity and realizing focusing along

the hyperbolic contour(Kinsler et al., 2000). Meanwhile, its favorable precision machinability ensures contour accuracy and interface finish of the inner wall to mitigate scattering losses(Pimenov et al., 2023). In frequency-domain modelling, for the frequency and material properties are fixed, the wavelength can also be determined. To improve the accuracy of finite element calculation results, the maximum mesh size in the computational domain was set to $\lambda/20$, where λ represents the sound wave wavelength(Yang et al., 2025). The attenuation coefficient of water was frequency-dependent (0.00625 Np/m at 0.5 MHz, 0.025 Np/m at 1 MHz, 0.05625 Np/m at 1.5 MHz, and 0.100 Np/m at 2 MHz), the excitation acoustic pressure was 30 kPa, and the ultrasonic transmission frequencies were 0.5 MHz, 1 MHz, 1.5 MHz, and 2 MHz respectively. The acoustic intensity distribution generated by ultrasound stimulation at different frequencies was calculated by the "Parametric Sweep" method. As shown in Fig. 1b-1e, the simulation results clearly reveal the variation patterns of focused acoustic pressure intensity and focal region morphology with different transmission frequencies. The ultrasound focal region exhibits a needle-shaped distribution. As the transmission frequency increases, the acoustic pressure amplitude increases, while the focal length gradually decreases, and the morphology becomes more slender.

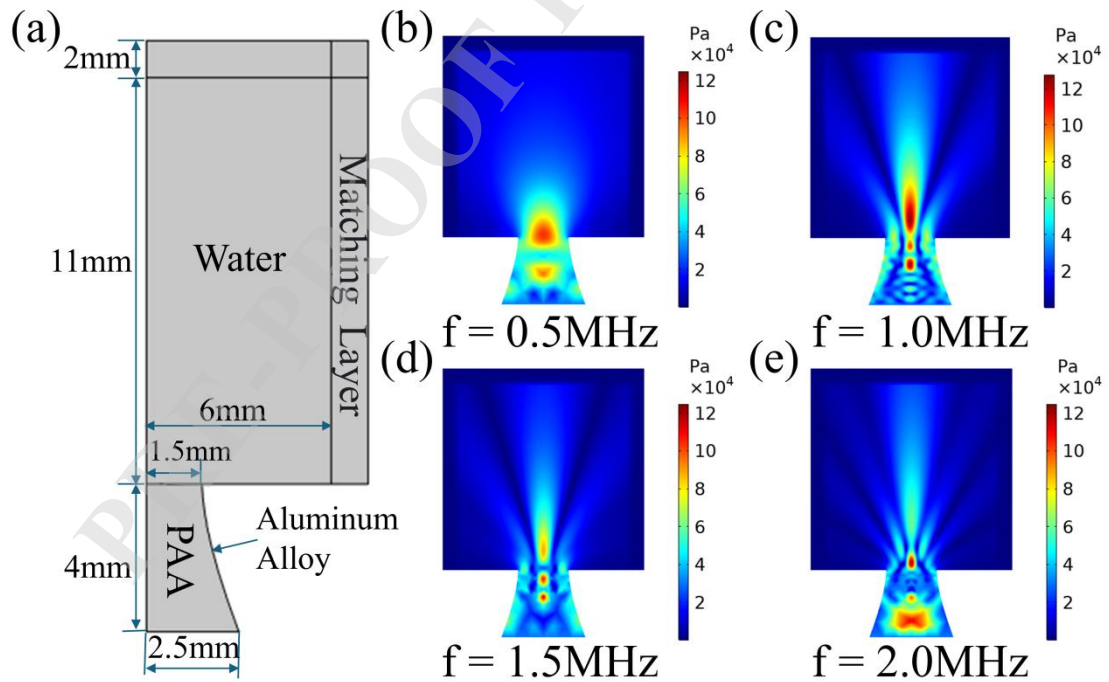


Fig. 1. Frequency selection diagram. (a) Simulation model. (b)-(e), the focused acoustic pressure intensity and focal region morphology.

Comprehensively considering the above simulation results and clinical application requirements, 1 MHz was ultimately determined as the ultrasonic transmission frequency in this study, which is within the safe range (200 kHz-2 MHz)(O'Reilly et al., 2024; Beisteiner et al., 2024).

2.1.3. Dimension Selection

During the simulation, the attenuation coefficient of water was 0.025 Np/m at 1 MHz, the excitation acoustic pressure was 30 kPa at the large-aperture end of the hyperbolic device, and the ultrasonic transmission frequency is 1.0 MHz. Hyperbolic acoustic-focusing transducers with different geometric dimensions are designed. As shown in Fig. 2, the acoustic intensity distribution characteristics of every transducer are obtained through simulation. The results indicate that changing the transducer dimensions alters the focal position and focal length.

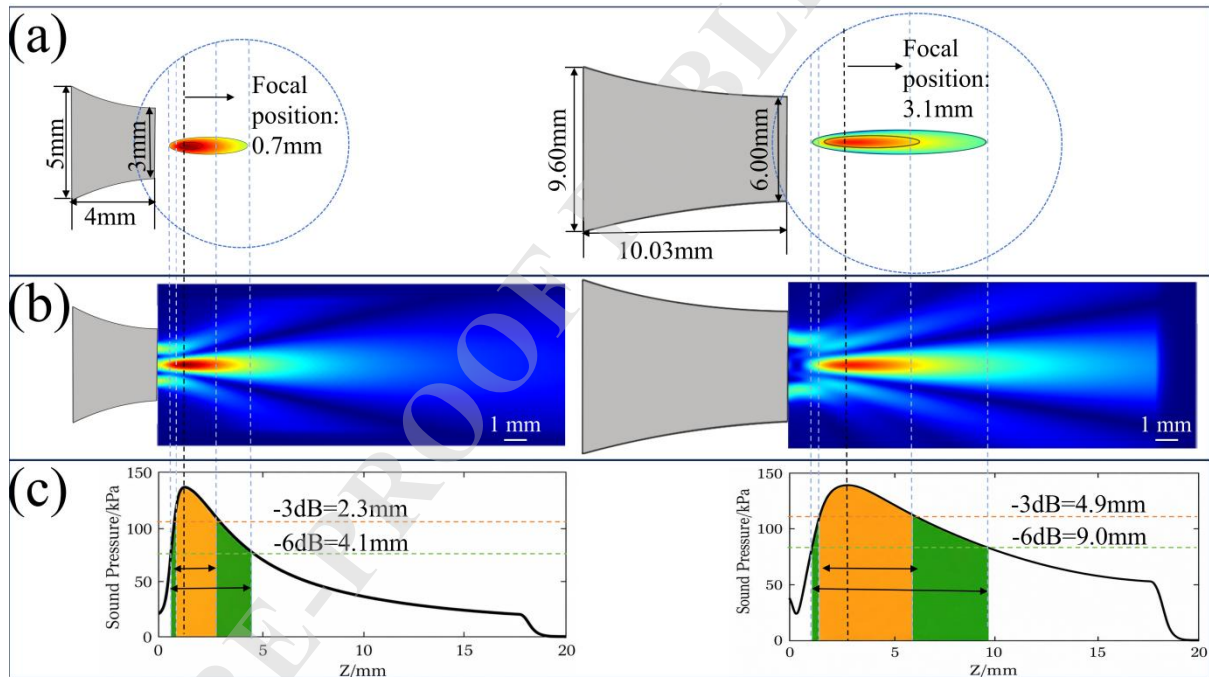


Fig. 2. Dimension selection diagram. (a) Dimensional parameters of the transducer (gray). The left diagram shows the hyperbolic device with the acoustic output end radius of 1.5 mm, the length of 4 mm and the focal position of 0.7mm (from the acoustic output end). The right diagram shows the hyperbolic device with the acoustic output end radius of 3 mm, the length of 10.03 mm and the focal position of 3.1mm. The vertical dotted lines show the continuity of these areas with parts (b) and (c). (b) Color acoustic model in the axial plane. Warmer colors represent higher acoustic pressure. (c) Axial acoustic pressure intensity distribution. The black line indicates that the waves converge toward the focal region, where the acoustic pressure is

maximum. The orange shaded region represents the -3 dB (71% pressure) width of the focal region, and the green shaded region represents the -6 dB (50% pressure or full width at half maximum (FWHM)) width. The left diagram shows focal lengths of 4.1 mm at -6 dB (50% pressure) and 2.3 mm at -3 dB (71% pressure). The right diagram shows focal length of 9.00 mm at -6 dB and 4.9 mm at -3 dB.

The geometric dimensions of the hyperbolic acoustic-focusing transducer are determined by the spacing and thickness of auricular acupoints (the selection of auricular acupoints is an acupoint prescription issued by clinicians specifically for patients with sleep disorders). As shown in Fig. 3, the minimum spacing between auricular acupoints is 5.5 mm. Studies have shown that the depth range of auricular acupoints is 1 mm-4 mm (Rana et al., 2020; Aydın et al., 2020). Combined with the acoustic field simulation results of hyperbolic acoustic-focusing transducers with different dimensions in Fig. 2. The hyperbolic acoustic-focusing transducer with the radius of 1.5 mm at the acoustic output end and the length of 4.0 mm was determined for subsequent auricular acupoints stimulation experiments.

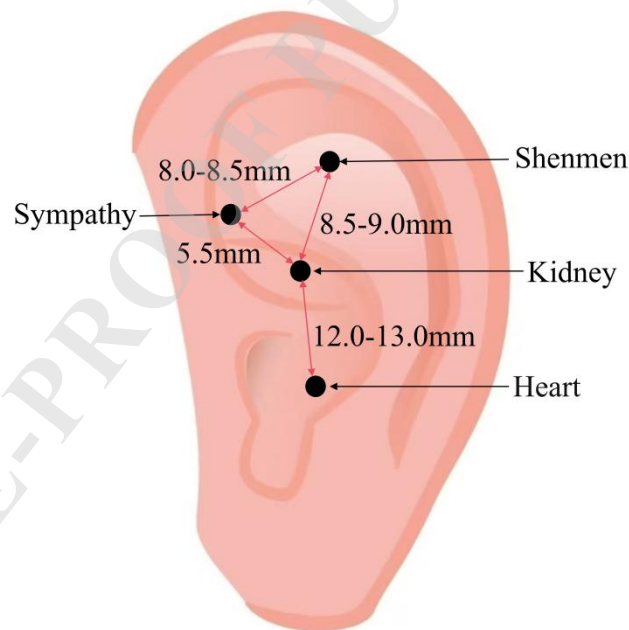


Fig. 3. Diagram of the distance between stimulated auricular acupoints.

2.2. Transducer Design and Focusing Mechanism

As shown in Fig. 4, the hyperbolic acoustic-focusing transducer was fabricated based on the determined parameters. The piezoelectric transducer unit (black region in Fig. 4) utilizes a

piezoelectric ceramic-electrode composite structure with the central frequency of 1.0 MHz. The body of the unit is composed of integrated PZT ceramic sheets and metal electrodes. The hyperbolic hollow focusing device (gray structure in Fig. 4) is made of aluminum alloy and filled with PAA hydrogel. Geometric parameters of the hyperbolic device: the effective radius at the acoustic input end is 2.5 mm, the effective radius at the acoustic output end is 1.5 mm, the wall thickness is 0.3 mm, and the axial length is 4.0 mm. The transducer and the hyperbolic device are bonded by a specialized silicone rubber adhesive. When the adhesive layer is configured to be sufficiently thin, it can efficiently transmit acoustic energy and reduce interface reflection loss(Rathod, 2020).

The ultrasonic focusing mechanism of this transducer takes the law of acoustic reflection as its core theoretical basis and enables directional acoustic energy focusing. The specific process is as follows: When 1 MHz ultrasonic wave generated by the piezoelectric transducer is transmitted through the adhesive layer to the acoustic input end of the hyperbolic device, the ultrasonic waves enter the device in a divergent form and undergo multiple reflections on the inner wall. This energy-convergence structure has a well-established research foundation in optics. It features large-aperture input, inner-wall reflective focusing, and small-aperture output. Fibrich et al. studied a tapered hollow duct using ray-tracing methods. They verified that the duct can achieve efficient laser energy transmission and convergence through multiple internal reflections. The physical mechanism is analogous to the acoustic focusing of the hyperbolic device in this work(Fibrich et al., 2013). As illustrated by the colored arrows in Fig. 4 (arrows of identical color converge at a single point), the ultrasonic propagation paths gradually converge toward the central axis of the hyperbolic device under its geometric constraint, ultimately forming a needle focal spot outside the device.

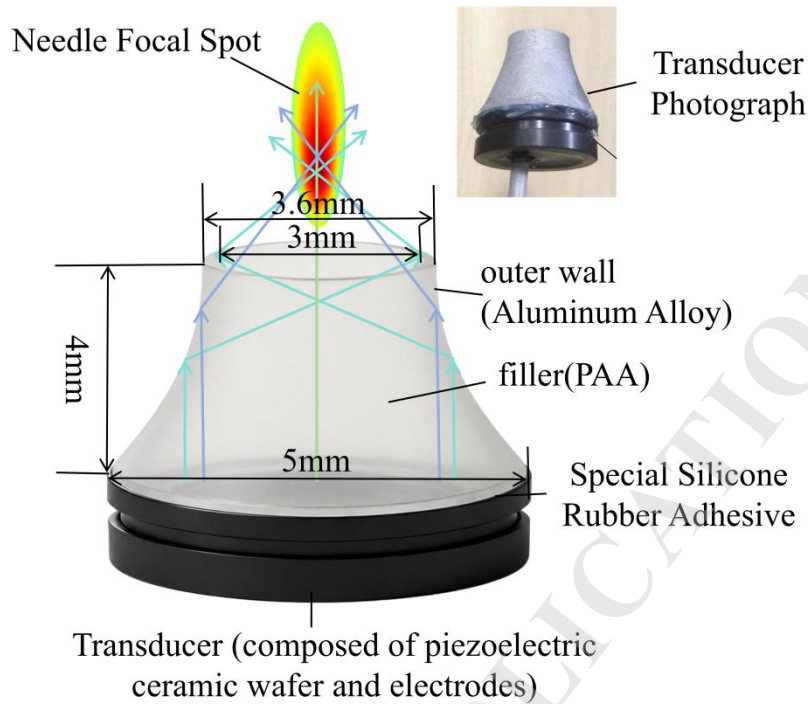


Fig. 4. Schematic diagram and photograph of the hyperbolic acoustic-focusing transducer. The aluminum-alloy hollow hyperbolic structure (input effective radius 2.5 mm, output effective radius 1.5 mm, wall thickness 0.3 mm, axial length 4.0 mm) is filled with PAA hydrogel and bonded to the 1.0 MHz piezoelectric transducer by special silicone rubber adhesive. Ultrasonic waves converge along the central axis under geometric constraint and produce a needle focal spot outside the device.

2.3. Laboratory Research

Hydrophone experiments were conducted to verify the acoustic focusing capability of the hyperbolic acoustic-focusing transducer. The experimental setup for measuring the acoustic field of the hyperbolic acoustic-focusing transducer is shown in Fig. 5. It mainly consists of an ultrasonic water tank acoustic field measurement system and a hyperbolic acoustic-focusing transducer, including a signal generator, a power amplifier, an oscilloscope, a hydrophone, a glass water tank, a three-dimensional free-motion mechanism, and a computer equipped with software for automatic acoustic field processing. The transducer used had the same dimensions as shown in the Fig. 4.

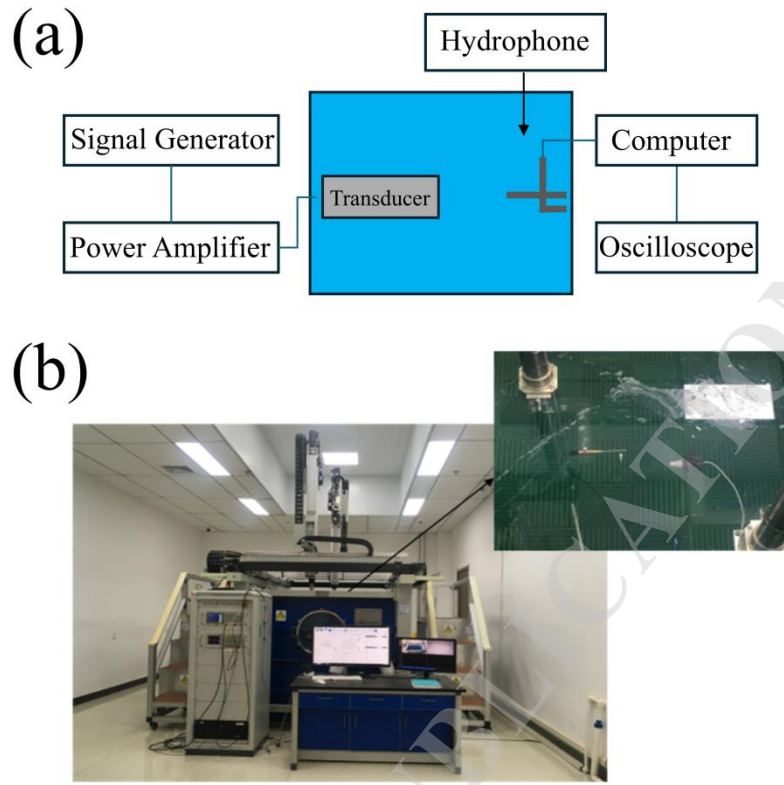


Fig. 5. Diagram of experimental equipment. (a) Overall schematic diagram of the experiment. (b) Overall physical setup of the experiment.

Fig. 6 presents the characterization results of the transducer acoustic field measured by a hydrophone (BTH-16M, Dibel, Hangzhou, China, 0.2 – 15 MHz, 1 mm sensitive element). Fig. 6(a) shows the three-dimensional acoustic pressure distribution in the x-y plane. The acoustic pressure is concentrated near the central axis ($y = 0$) and decays rapidly with increasing transverse distance, exhibiting typical beam focusing characteristics. Fig. 6(b) depicts the acoustic pressure–position curve along the axis ($y = 0$). The acoustic pressure reaches its peak at $x = 0.6$ mm and decreases monotonically toward both sides. The axial -3 dB and -6 dB beam widths are 1.8 mm and 2.8 mm, respectively. Compared with the simulation results shown in the left panel of Fig. 2(c), the relative error of the peak acoustic pressure is 14.19%, and the errors of the axial -3 dB and -6 dB beam widths are 17.85% and 34.7%, respectively, all within the acceptable range (Krokhmal et al., 2025). Slight deviations exist between measured and simulated peak acoustic pressure. The primary cause is spatial averaging. The actual effective sensing size of the hydrophone is far larger than its nominal size, which smooths the real peak pressure. Other factors such as imperfect hydrophone frequency response, tiny alignment shifts

during scanning, and weak acoustic attenuation in water work together and lower the measured pressure (Martin, Treeby, 2019). Fig. 6(c) displays the normalized transverse acoustic pressure distributions at three characteristic axial depths ($x = 0.2$ mm, $x = 0.6$ mm, and $x = 3$ mm). As can be observed, the transverse beam profile is relatively wide before the focus ($x = 0.2$ mm, FWHM = 1.89 mm), narrows significantly at the focus ($x = 0.6$ mm, FWHM = 1.28 mm), and diverges again beyond the focus ($x = 3$ mm, FWHM = 2.38 mm). This convergence–focusing–divergence evolution of the acoustic beam confirms that the field generated by the transducer is a focused acoustic field.

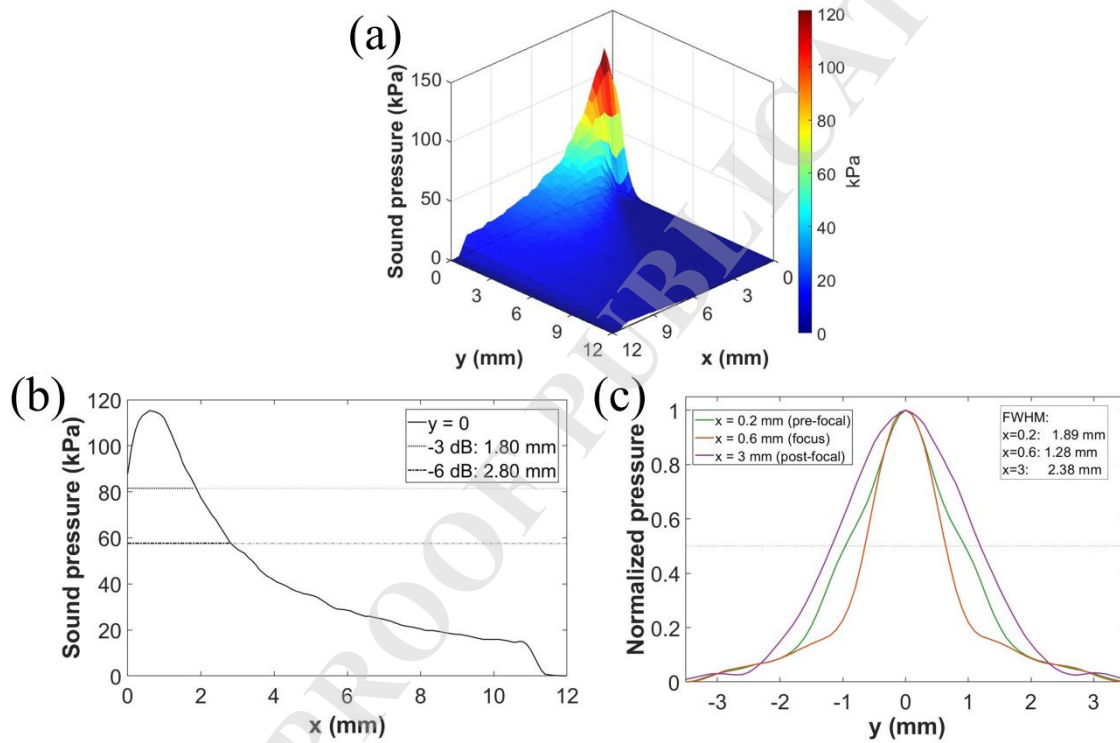


Fig. 6. Characterization of the acoustic field measured by a hydrophone. (a) Three-dimensional acoustic pressure distribution in the x-y plane. (b) Acoustic pressure – position curve along the axis ($y = 0$). (c) Normalized transverse acoustic pressure distributions at $x = 0.2$ mm (pre-focus), $x = 0.6$ mm (at the focus), and $x = 3$ mm (post-focus).

2.4. Clinical Design

2.4.1 Study Subjects

80 eligible patients with circadian rhythm disruption and sleep disorder were recruited in this study. These patients were from Xi'an Hospital of Traditional Chinese Medicine. Online forms were used to select potential participants based on inclusion or exclusion criteria. First,

participants were selected based on diagnostic criteria established in the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV). Second, participants were required to meet the following criteria: aged between 18 and 70 years, PSQI score > 7 , Epworth Sleepiness Scale (ESS) score < 16 , Hamilton Depression Scale (HAMD) score < 17 , the ability to comprehend the study questionnaires. Additionally, patients who did not meet the diagnostic and inclusion criteria or had comorbidities (such as organic diseases, severe ear trauma, cognitive deficits, and communication difficulties) were excluded during the selection process.

2.4.2 Experimental Design

This study used a randomized controlled clinical trial design. Concealed allocation was performed using the envelope method. 80 patients were randomly assigned to the treatment group (ultrasound stimulation group) and the control group (auricular bean pressure group) in a 1:1 ratio, with 40 patients in each group. The selected auricular acupoints for both groups were Heart Point, Kidney Point, Shenmen Point, and Sympathy Point. Both groups received treatment for 4 weeks, 5 times per week, with a 12-week follow-up period. The scores of questionnaires, including the PSQI, Insomnia Severity Index (ISI), Athens Insomnia Scale (AIS), ESS, Hamilton Depression Rating Scale-17 (HAMD-17), and Hamilton Anxiety Rating Scale-14 (HAMA-14), were measured before treatment, after the 4-week treatment, and during follow-up.

The working mechanism of the LIFU therapeutic device used in the treatment group is as follows: as shown in Fig. 7a, a waveform generator is connected to an oscilloscope for real-time waveform monitoring. The waveform generator drives the transducer. The transducer converts the electrical signal into ultrasonic signal, which acts on auricular acupoints aiming to intervene in insomnia symptoms through neuroregulatory mechanisms (Duff et al., 2024). To improve operational convenience, we designed personalized earmuffs made of transparent rubber, with customized perforations at the positions of auricular acupoints to secure the transducers. To evaluate the intervention effect, ECG signals are collected by an ECG monitor and transmitted to the computer for real-time analysis (He et al., 2025). As shown in Fig. 7b, the propagation path of ultrasonic stimulation of auricular acupoints penetrates the skin-fat-bone tissue sequentially. As shown in Fig. 7c, auricular acupoints are stimulated with 50% duty cycle and 1 MHz frequency. The voltage parameter is adjusted according to patients' tolerance. The stimulation mode is bilateral ear stimulation: each acupoint is stimulated for 5 minutes, with a 5-minute interval. As shown in Fig. 7d, when auricular acupoints are stimulated with the given parameters, the simulation results verify that the focused ultrasound energy can be accurately delivered to

the fat-bone interface.

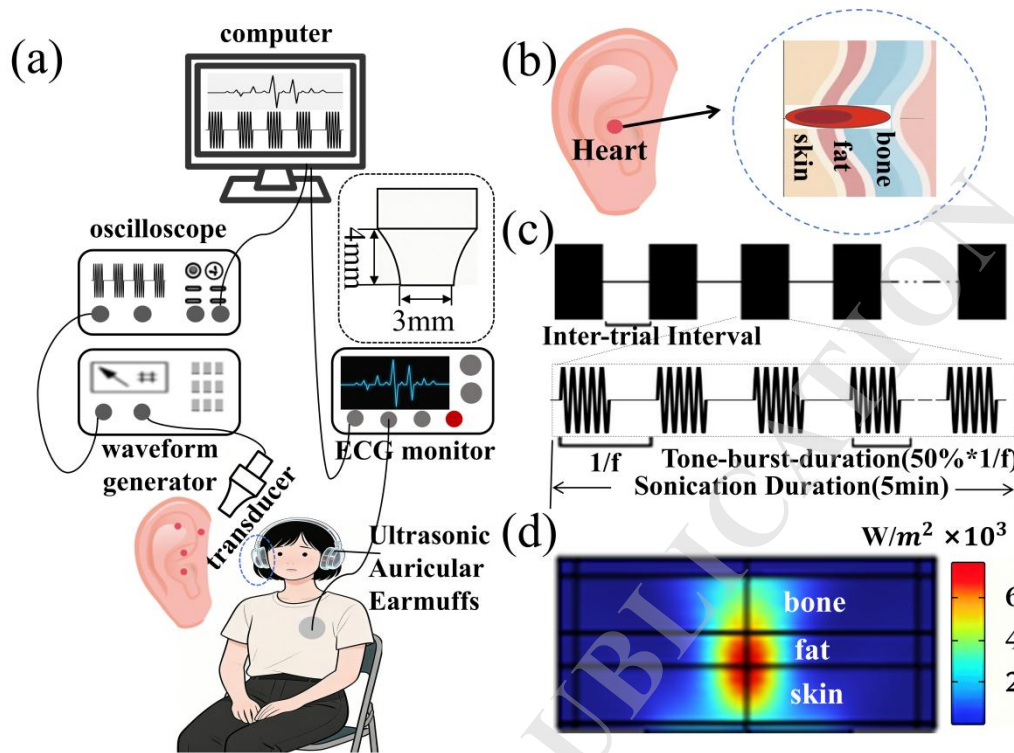


Fig. 7. Diagram of the system framework for the treatment group. (a) Therapeutic system. (b) Tissue structure penetrated by ultrasound. (c) Parameter settings. (d) Simulation results.

2.4.3 Operational Methods

These operational methods were determined as a reasonable option through repeated practice with the participation of clinicians. Treatment Group: Patients were seated upright. Bilateral auricular skin was cleaned with 75% ethanol. The probe of the ultrasonic therapy device was secured by earmuffs. Each acupoint was stimulated for 5 minutes, one time a day. ECG signals were collected simultaneously. Control Group: Patients were seated upright. Bilateral auricular skin was cleaned with 75% ethanol. Apply the Vaccaria seed to the auricular acupoints. Patients perform self-massage on the auricular acupoints 3-4 times a day, 5 minutes each time, alternating between the two ears.

2.4.4 Data Processing

ECG Data Processing: Human ECG signals are weak physiological electrical signals acquired via skin-surface electrodes(Książek et al., 2025). These signals inevitably interact with the

external environment and contain many kinds of noises. The signal noises are removed by wavelet transform(Khalili et al., 2024). The collected ECG signals were decomposed into different scale spaces based on their frequency components, and subsequently the wavelet coefficients were processed. Finally, the processed wavelet coefficients were reconstructed by inverse wavelet operation, and then the ECG signal with noise removal was obtained.

The processed ECG data were used to construct a sleep staging model, which specifies the posterior probability of the sleep state as a function of time and is mathematically denoted as $P(\text{sleep time})$ or $P(\text{wake time})$.

Initially, the model of the posterior probability distribution was selected using a basic logistic regression function. The expression:

$$P(t) = \frac{1}{1 + \exp(\beta t + \alpha)}, \quad (1)$$

the parameter β represented the direction and steepness of the curve, and the parameter α represented the position.

In the experiment, we set the sleep model to a Bernoulli variable where wakefulness is 0 and sleep is 1. The Bernoulli variable of the sleep data was defined by the logistic regression function, and the final expression:

$$P(\text{sleep}|t_i) = \text{Ber} \left(\frac{1}{1 + \exp(\beta t_i + \alpha)} \right). \quad (2)$$

We used a Bayesian approach(Aiello et al., 2023; Dastin-van Rijn, Widge, 2025) to find the appropriate α and β , which assumed that these two parameters obeyed two normal distributions, the probability density function of the positive distribution:

$$f(x|\mu, \tau) = \sqrt{\frac{\tau}{2\pi}} \exp \left(-\frac{\tau}{2} (x - \mu)^2 \right), \quad (3)$$

where, μ represented the mean value, τ represented the precision.

The most suitable values of α and β were found using the Markov Chain Monte Carlo (MCMC)(Duff et al., 2024) algorithm. Based on this model, the sleep probability can be determined at any given time before, during and after treatment for patients.

Questionnaire Data Processing: SPSS 26.0 statistical software was used for data processing and

analysis. For categorical variables, frequency (n) and percentage (%) were used for statistical description, and the Chi-square test was applied for intergroup comparisons. For continuous variables, normality test was first performed. Data conforming to normal distribution were expressed as mean $\pm$ standard deviation ($\bar{x} \pm S$). Intergroup differences were analyzed using independent-samples t-test, and intragroup comparisons were conducted using repeated-measures analysis of variance (ANOVA). Data with non-normal distribution were presented as median (interquartile range) [M (P25, P75)]. Intergroup comparisons were analyzed using Mann-Whitney U test, and intragroup comparisons were conducted using Wilcoxon signed-rank test. All statistical tests used a significance level of $\alpha = 0.05$, and $p < 0.05$ was considered statistically significant.

3. Results

3.1. Cases

A total of 80 patients were included in this study, with 40 patients in the treatment group and 40 in the control group. The chi-square test or independent-samples t-test was used to compare gender, age, and disease duration between the two groups. All $P > 0.05$, indicating no statistically significant differences between the two groups and demonstrating that the two groups were comparable (see Table 1).

Table 1. Comparison of Gender, Age, and Disease Duration Between the Two Groups of Patients

Group	Gender (Cases): Male/Female	Age (years)	Disease Duration (years)
Treatment Group	12/28	48.02 $\pm$ 13.20	5.00(2.00,7.50)
Control Group	11/29	47.05 $\pm$ 11.93	5.50(4.00,8.00)
P	0.860	0.729	0.307

3.2. Efficacy Evaluation

As shown in Fig. 8, compared with pre-treatment values, the scores of all questionnaires in both groups were significantly reduced after treatment and during follow-up period, with statistically significant differences observed ($P < 0.05$). This indicates that both treatment methods can effectively enhance therapeutic efficacy. Meanwhile, auricular bean pressure therapy in the control group is a commonly used and effective TCM approach for the treatment of sleep disorder (Zheng et al., 2025). Thus, stimulating auricular acupoints with the novel hyperbolic acoustic-focusing transducer achieves equivalent therapeutic efficacy.

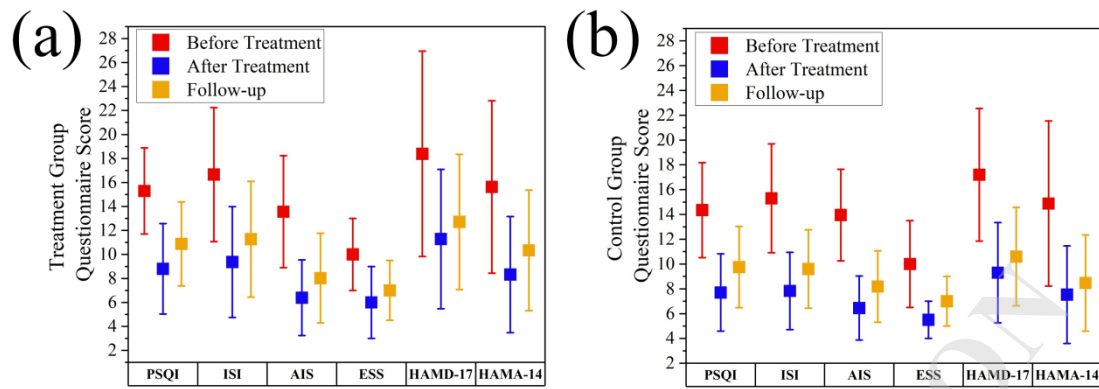


Fig. 8. Diagram of the statistical results for the questionnaire (a) Results of the Treatment Group; (b) Results of the Control Group.

In addition, the treatment group assessed patients' sleep duration before, during, and after treatment by analyzing ECG signals. As shown in Fig. 9, the average nightly sleep duration of patients increased from 4.04 hours before treatment to 5.26 hours during treatment, and finally to 6.82 hours after treatment. These results indicate that treating sleep disorder by stimulating auricular acupoints with the novel hyperbolic acoustic-focusing transducer is effective.

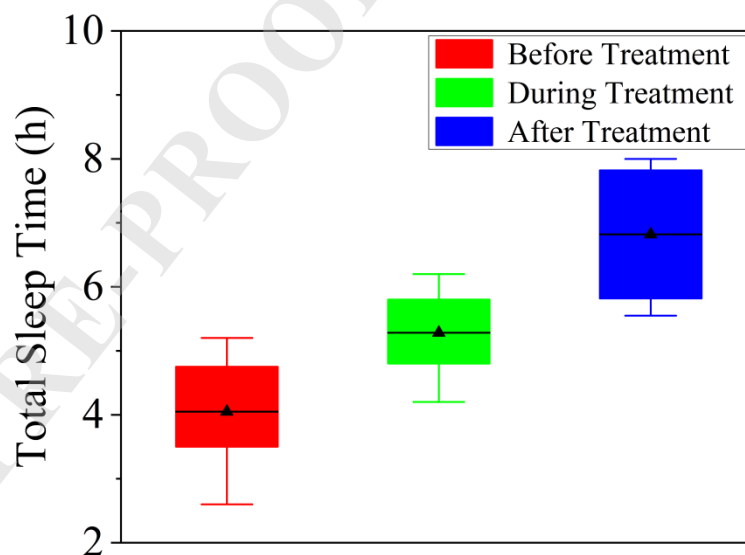


Fig. 9. Diagram of sleep duration results for the treatment group.

3.3. Safety Evaluation

All vital signs of participants, including blood pressure, heart rate, body temperature, and respiration, remained within the normal range throughout the 4-week treatment period. All participants completed the treatment without incident.

Mechanical Index (MI) and Thermal Index (TI) have been proposed as objective evaluation indicators for the safety of ultrasonic equipment (Abbott, 1999). In this study, the MI is calculated in accordance with the IEC 62359 standard (International Electrotechnical Commission [IEC], 2017):

$$MI = \frac{p_{r,3}}{\sqrt{f_c}}, \quad (4)$$

where $p_{r,3}$ is the rarefactional peak pressure at the focus (MPa), and f_c denotes the ultrasonic center frequency (MHz). Under linear acoustic field conditions, the rarefactional peak negative pressure equals the acoustic pressure amplitude. Substituting $p_{r,3}=0.12989\text{MPa}$ and $f_c=1\text{MHz}$, we obtain $MI \approx 0.13$. This value is lower than 0.3, indicating a low risk of cavitation and mechanical damage under ultrasonic excitation (Apfel, Holland, 1991).

Regarding the calculation of the TI, the ultrasonic focus acts on the auricular cartilage in this study. Therefore, the Bone Thermal Index (TIB) is adopted for thermal safety assessment. Acoustic energy undergoes significant attenuation in the soft tissue layer along the ultrasonic propagation path. The Soft Tissue Thermal Index (TIS) is lower than TIB, so thermal risks can be neglected (O'Brien, 2007). The peak acoustic pressure at the focal plane $p_{focus}=0.12989\text{MPa}$ is obtained from two-dimensional axisymmetric acoustic field simulations. The -6 dB beam cross-sectional area $A_{b,6}=7.34 \times 10^{-3}\text{cm}^2$ is acquired via radial line integration. The spatial-peak temporal-average acoustic intensity is calculated as follows:

$$I_{SPTA} = \frac{1}{2} \times DC \times \frac{p_{focus}^2}{\rho c} = 281.274\text{mW/cm}^2, \quad (5)$$

where DC is the ultrasonic pulse duty cycle ($DC=0.2$), and ρc represents the acoustic impedance ($1.5 \times 10^6\text{Pa}\cdot\text{s/m}$). The temporal-averaged acoustic power within the -6 dB focal region is expressed as: $P_{c,6}=I_{SPTA} \cdot A_{b,6} \approx 2.064\text{mW}$, TIB (in accordance with IEC 62359 standards):

$$TIB = \min\left(\frac{I_{SPTA}(\text{mW/cm}^2) \cdot P_{c,6}(\text{mW})}{50}, \frac{P_{c,6}(\text{mW})}{4.4}\right) \approx 5.62 \times 10^{-3}. \quad (6)$$

This result demonstrates that the risk of thermal effects under the current ultrasonic excitation conditions is low.

4. Discussion

For the selection of acupoint, both ultrasound stimulation and auricular bean pressure therapy stimulate sleep-related auricular acupoints, thereby achieving regulation of visceral functions, calming the mind, and harmonizing yin and yang (Lu et al., 2022; Guo et al., 2024; Jin et al., 2020). Auricular acupoint stimulation can bidirectionally regulate the sleep-wake cycle through the meridian conduction mechanism, effectively balancing the excitation and inhibition processes of the cerebral cortex. This therapy shortens sleep onset latency, reduces the frequency of nocturnal awakenings, prolongs deep sleep duration, and alleviates emotional disturbances

associated with sleep disorders(Hu et al., 2024).

In practical clinical applications, the novel ultrasound therapy approach overcomes key limitations of TCM acupuncture. 1. Reducing dependence on physicians' expertise: The efficacy of traditional acupuncture largely relies on physicians' technical operational proficiency, leading to inconsistent therapeutic effects. The ultrasound stimulation protocol for auricular acupoints proposed in this study standardizes the treatment process by setting treatment parameters, reduces reliance on professional expertise, and enhances broad applicability(Wang et al., 2022). 2. Improving patient acceptance: Some patients refuse acupuncture due to fear of needles, making treatment difficult to implement. The ultrasound stimulation protocol is a non-invasive approach, enhancing treatment compliance. 3. Enhancing treatment safety: Traditional acupuncture carries the risk of infection caused by puncture. Some auxiliary drugs may induce side effects. The ultrasound stimulation protocol requires no puncture or drugs, fundamentally eliminating these risks and improving safety(Sarica et al., 2022; Radjenovic et al., 2022).

For the effectiveness and safety of auricular ultrasound stimulation for treating sleep disorder. Compared with the auricular bean pressure therapy, ultrasound therapy has the advantage of enabling the formulation of personalized treatment plans based on patients' individual differences, ensuring the comfort, accuracy, and effectiveness of treatment. Using the parameters selected in this study, the maximum acoustic intensity induced by the hyperbolic acoustic-focusing transducer is 0.428 W/cm^2 , which falls within the physiological tolerance range of biological tissues(Radjenovic et al., 2022). No adverse reactions were observed in patients after ultrasound stimulation, confirming the safety of LIFU in the treatment of sleep disorders. In addition, objective indicators such as electroencephalography (EEG)(Arnal et al., 2020), functional magnetic resonance imaging (fMRI)(Vieira et al., 2023), and near-infrared spectroscopy (NIRS)(Chen et al., 2020) can be introduced to provide more accurate assessment of brain function status, helping to better evaluate the effectiveness of ultrasound therapy for sleep disorders(Bao et al., 2023).

5. Conclusions

This study designed and fabricated the novel hyperbolic acoustic-focusing transducer through theoretical simulation and laboratory experiments, aiming to treat sleep disorder by stimulating auricular acupoints. This transducer was clinically applied to stimulate the auricular acupoints of patients with sleep disorder for treatment. Clinical experimental results showed that the sleep

duration of patients significantly increased after one treatment course. In addition, depressive and anxiety symptoms were alleviated, confirming the feasibility and effectiveness of this transducer in treating sleep disorder. Interviews with patients about their feelings after treatment indicated that ultrasound stimulation of auricular acupoints had no adverse effects. Our method is expected to serve as a non-invasive solution for treating patients with sleep disorder, expanding the application of ultrasound in the treatment of mental disorders.

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CONFLICT OF INTEREST

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

AUTHORS' CONTRIBUTIONS

S.Z., X.-Y.L., Z.-Z.R., J.-X.T., L.-W.G., J.T and M.-Y.L. designed and performed the main experiments and measurements. J.L., J.H., J.-M.A., N.Q., F.-L.F., X.-Y.L. and S.Z. designed a hyperbolic acoustic-focusing transducer and evaluated its performance. S.Z., X.-Y.L., Z.-Z.R., J.L., J.-X.T., L.-W.G., J.T and N.Q. participated in the experiments and mechanism analysis. S.Z., M.-Y.L., Z.-Z.R., X.-Y.L., F.-L.F., and J.L. wrote the manuscript. All authors reviewed and approved the final manuscript.

ETHICAL APPROVAL

The study was conducted in accordance with the Declaration of Helsinki and approved by the Ethics Committee of [Xi'an Hospital of Traditional Chinese Medicine (Approval No.: LLSCPJ2023066)]. Informed consent was obtained from each participant. All data were anonymized prior to analysis.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

HUMAN RIGHTS STATEMENTS AND INFORMED CONSENT

All procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration of 1964 and later versions. Informed consent was obtained from all patients for being included in the study.

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