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A Home Efficacy Multi-Modal Intelligent Evaluation System for Wearable Treatment Equipment of Insomnia Through Integration Between Traditional Chinese Medicine and Modern Medicine

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ABSTRACT

Wearable treatment equipment has become a hot topic among traditional Chinese medicine (TCM) researchers. The wearable instrument for transcutaneous electrical stimulation therapy (TEST) developed by our research team has unique advantages in treating insomnia induced by the heart disorder due to phlegm and fire (HDPF). However, the treatment efficacy of the instrument has not been verified by multi-modal data, which limits its application at home. In fact, there is no intelligent efficacy evaluation system for the home treatment of insomnia with the instrument. To make up the gap, this paper attempts to build a home efficacy multi-modal intelligent evaluation system (HEMIES) for this wearable TEST instrument, drawing on the latest technologies of medicine and informatics. Taking HDPF-induced insomnia as an example, the authors firstly set up an index system of the HEMIES for HDPF-induced insomnia, and constructed a conceptual model of the HEMIES. Next, the syndrome images of TCM were fused with the text data of modern medicine, and used to evaluate the treatment efficacy and complete the HEMIES. Finally, 33 patients with HDPF-induced insomnia were recruited to treat the disease with the wearable TEST instrument at home. The observed results show that the prediction accuracy rate of the HEMIES was as high as 90.63%, indicating that the system boasts a good prediction ability and a high value for home application. Our HEMIES realizes the objective evaluation of the home treatment efficacy of the wearable TEST instrument in the absence of TCM practitioners, and provides a reference for the efficacy research of other TCM treatment equipment in home treatment.

1. INTRODUCTION

Wearable treatment equipment is critical to the modernization and digitization of traditional Chinese medicine (TCM). In recent years, many researchers have attempted to develop portable, integrated, and miniaturized wearable TCM treatment equipment based on the latest sensing technology, aiming to promote the objective and quantitative development of TCM [1]. Non-drug therapy is an important means of disease treatment [2]. For example, low-frequency pulse electrical stimulation, capable of exciting neuromuscular tissue, promoting local blood circulation, and relieving pain [3], has unique advantages in the treatment of insomnia [4, 5].

To treat insomnia at home without any drug, our research team designed a wearable instrument for transcutaneous electrical stimulation therapy (TEST), and demonstrated its simplicity and speed in home treatment of insomnia. The home efficacy of this wearable TCM treatment equipment needs to be evaluated by a multi-modal intelligent evaluation system (MIES). This paper takes the heart disorder due to phlegm and fire (HDPF), a common clinical syndrome of insomnia, as an example to introduce a novel home efficacy MIES (HEMIES).

Many researchers have probed deep into TCM efficacy evaluation, and they all agree that TCM syndrome as a defining feature of TCM efficacy [6]. According to the previous studies on the diagnosis and treatment efficacy of insomnia, the HDPF is characterized by following symptoms: red face, red to crimson red tongue, thin yellow, yellow greasy, or little moss, etc. [7, 8]. Therefore, tongue images [9] and face images [10] are often used to evaluate the severity of HDPF.

Modern medicine offers lots of widely recognized and highly feasible indicators, which can assist with the evaluation of TCM efficacy [11]. For instance, the Pittsburgh Sleep Quality Index (PSQI) [12] has become the primary basis for self-evaluation of sleep status, an important metric of the treatment efficacy of insomnia. The data on sleep structure, namely, total duration, deep sleep duration, light sleep duration, and awake duration, are the main indices for sleep quality evaluation [13]. Hence, the text data of modern medicine could contribute to the efficacy evaluation of insomnia treatment.

The tongue and face features of TCM contain key features of the HDPF. Manual diagnosis of this insomnia syndrome is limited by experience, and difficult to make objective judgement. To solve the problem, image processing algorithms have been introduced to recognize TCM images [14], trying to measure and extract features of tongue and face images of TCM objectively and accurately. Meanwhile, multi-modal data fusion [15] has been successfully applied to intelligent analysis, and proved capable of converting and fusing various types of data (e.g., texts, images, and videos), providing a methodological reference for this research.

Through the above analysis, this paper decides to construct a HEMIES for the wearable TEST instrument in home treatment of HDPF-induced insomnia. The proposed system fuses the syndrome images of TCM with the text data of modern medicine.

2. LITERATURE REVIEW

Table 1 summarizes the research gap in treatment efficacy evaluation. The existing evaluation approaches for treatment efficacy in TCM lack uniform standards and characteristics indices of TCM. The current standards are simple imitations of those of modern medicine. The few available treatment efficacy evaluation systems are only applicable to postoperative treatment and rehabilitation evaluation of major clinical diseases. None of them can be directly applied to home treatment of diseases.

3. METHODOLOGY

Based on the literature review, this paper firstly sets up an index system of the HEMIES for HDPF-induced insomnia, and assigns a weight to each index by the Delphi method, creating a conceptual model of HEMIES. After that, tongue and face features were extracted objectively with target detection and image analysis algorithms. Finally, TCM syndrome images were fused with the text data of modern medicine, and used to evaluate the treatment efficacy of HDPF-induced insomnia, marking the completion of HEMIES development.

3.1 Index system construction

The previous studies have shown the significance of observation to syndrome differentiation and treatment. As a diagnosis approach, observation offers highly intuitive information of syndrome differentiation. Face diagnosis is an important aspect of TCM observation. Face color, the external expression of human viscera, Qi, and blood reflect the changes of human diseases. TCM theories hold that the tongue is connected with the viscera. If the Qi and blood of viscera are calm, the tongue will be pale red. If they are out of balance, blood stasis and Qi stagnation/obstruction will ensue, and the color of the tongue will change.

Kim et al. [16] believed that insomnia patients have strikingly unique tongue and face features. According to the TCM Clinical Guidelines of Insomnia Research Group (WHO/WPO) (2016 edition), red tongue, thick moss, and red face can be observed on the tongue and face images of patients with HDPF-induced insomnia. Preliminary studies have shown that the severity of HDPF-induced insomnia increases with the redness of the tongue and face, and the thickness of moss. Therefore, the type and severity of insomnia can be identified based on face color, tongue color, and moss.

In modern medicine, PSQI is the most widely used self-rating sleep quality scale for evaluating the treatment efficacy of insomnia. The data on sleep structure, including total duration, deep sleep duration, light sleep duration, and awake duration, intuitively reflect the quality of sleep. Drawing on the relevant literature, this paper preliminarily builds up an index system for HEMIES, which consists of eight secondary indices and four primary indices (Table 2).

To streamline the index system and preserve strongly related indices only, experts and scholars in the field of TCM diagnosis and treatment of insomnia were invited to rate the importance of each index against a five-point scale. Two rounds of ratings were carried out anonymously based on the Delphi method. Based on the scores, the core indices were identified and ranked by importance.

Specifically, consultation forms were sent to 25 experts from 10 TCM colleges. All of them hold senior professional titles in TCM diagnosis and treatment of insomnia. Located in Beijing, Heilongjiang, Henan, Jiangsu, Zhejiang, Hubei, and Guangdong Province, the ten colleges are approximately evenly distributed in eastern, western, southern, northern, and central regions of China. In this way, the most representative and authoritative experts were selected, with a balanced regional distribution. A total of 23 experts made a reply.

Table 1. Research gap

Research	Methodology	Limitations
Zheng [17], State Administration of Traditional Chinese Medicine [18] and Feng et al. [19]	Guiding principles for clinical research of new Chinese medicine; diagnostic criteria for treatment efficacy of TCM diseases and syndromes	Lacking uniform standards and characteristics indices of TCM
Lee et al. [20] and Zhang et al. [21]	Evaluation with indices of modern medicine; randomized controlled experiment	Lacking characteristics indices of TCM; Only applicable to clinical evaluation
Liu et al. [22]	Computed tomography (CT) perfusion imaging	Difficult to use at home

Table 2. HEMIES index system

Serial number	Primary indices	Secondary indices
1	Tongue image	Tongue redness, moss thickness
2	Face image	Face redness
3	Modern medicine scale	PSQI score
4	Sleep structure	Sleep duration, deep sleep duration, light sleep duration, awake duration

In the first round of consultation, 61% of the experts suggested evaluating sleep duration, deep sleep duration, light sleep duration, and awake duration comprehensively, and transforming the evaluations into a score of sleep structure, in order to facilitate sleep quality evaluation. Therefore, the second round of consultation was conducted after the adjustment of the index system. During the second round, the experts further confirmed the level and importance of each index. Through the two rounds of consultation, three secondary indices were deleted. After the deletion, the expert opinions were basically consistent. Therefore, the final HEMES index system contains five secondary indices and four primary indices. The indices and weights of the final system are presented in Figure 1.

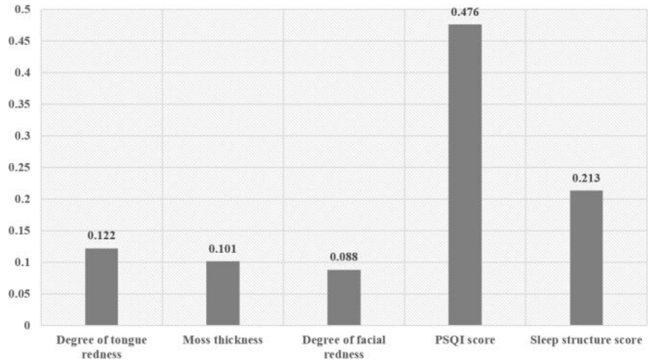


Figure 1. Indices and weights of the final system

3.2 HEMIES conceptual model

Based on the final index system, a conceptual model of HEMIES was established, involving five secondary indices and four primary indices (Figure 2).

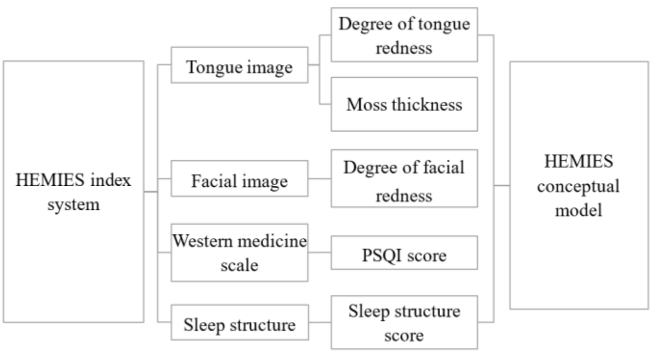


Figure 2. HEMIES conceptual model

3.3 HEMIES design and implementation

This paper intents to build an HEMIES based on the above results. According to the multi-modal health data of insomnia patients, the system should be able to intelligently identify the specific TCM syndrome, recommend a personalized physiotherapy with TCM TEST equipment, and evaluate the treatment efficacy. Through a closed loop of evaluation-treatment-evaluation, the HEMIES ought to enable the evaluation and dynamic monitoring of home treatment efficacy for HDPF-induced insomnia, and improve the home treatment efficacy by optimizing the therapy through big data analysis. Figure 3 explains the procedure of severity analysis and therapy recommendation of the HEMIES.

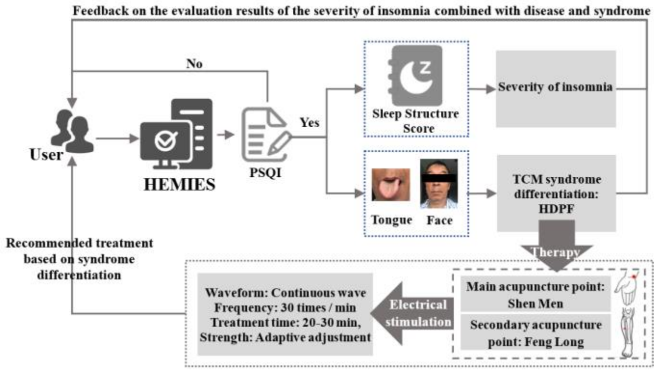


Figure 3. Severity analysis and therapy recommendation

3.3.1 HEMIES design

(1) Overall design

Based on big data and cloud computing, the HEMIES was designed with the following modules: a data collection module at the front end; a smart cloud module for data storage and data analysis at the middle end; a data feedback and health services module at the back end. The overall design of the system is illustrated in Figure 4.

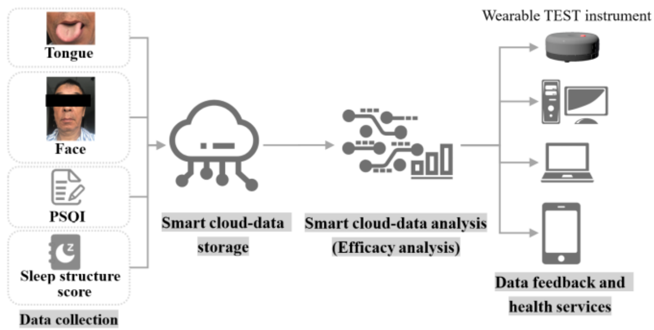


Figure 4. Overall design

The data collection module acquires four kinds of data: tongue image, face image, PSQI, and sleep structure. The collected data are encrypted and uploaded to the smart cloud module for storage. In the smart cloud module, the data are analyzed, and processed at the data processing center.

To realize fast and precise data analysis, multi-modal data were adopted to jointly evaluate the severity of insomnia, generate an evaluation report, and send it back to the user via computer or cellphone. Every week, each user can learn the severity of his/her insomnia, and check the evaluation report in HEMIES.

(2) System architecture

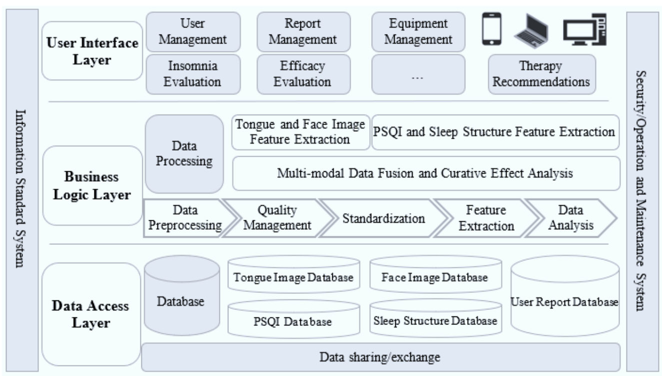


Figure 5. System architecture

Guided by the principle of high cohesion and low coupling, our HEMIES was designed with an architecture of three layers: a user interface layer (UIL), a business logic layer (BLL), and a data access layer (DAL). These layers are interconnected through interfaces. The functions and services provided by UIL can be accessed with the aid of network transmission technologies, such as Wide area network (WAN), wireless local area network (WLAN), and local area network (LAN). Figure 5 shows the architecture of our HEMIES.

The UIL is responsible for interaction with the user. The data imported and exported by this layer convey and feedback the user needs. The main functions of the UIL include severity evaluation, treatment efficacy evaluation, and report management. The data can be transmitted from this layer to the BLL without any logical judgement. The processing results will be fed back to the UIL, once they can provide a good user experience.

The BLL logically judges and executes specific problems, and connects to the DAL after receiving the user instructions from the UIL. As data and instructions are transmitted among the three layers, the user's health data are processed logically to extract and fuse the features of multi-modal data. Then, the results of treatment efficacy evaluation are sent back to the UIL.

The DAL works as a data management system, composed of a tongue image database, a face image database, PSQI database, a sleep structure database, and a user report database. On this layer, the user data can be added, deleted, modified, and queried. The operation results can be fed back to the BLL.

3.3.2 System implementation

(1) Feature extraction

Tongue color, moss thickness, and face color are important features for TCM syndrome differentiation and treatment. Traditionally, tongue features are extracted manually with a low accuracy and completeness. Computer image detection and recognition help to extract features of TCM syndromes objectively, which contribute to the precision of TCM diagnosis and treatment.

(2) User-side image standardization

After hearing a voice prompt, the user takes a video 15cm away from the lens in natural light at 10am. The shooting environment prevents the ambient light sources from affecting image quality, and facilitates the standardization of images. Then, each frame of the video was resized to 608×608, and denoised by the Butterworth filter, for the image is severely distorted by Moiré pattern during bicubic interpolation:

$$B(X,Y) = \sum_{I=0}^{3}\sum_{J=0}^{3} A_{IJ} \times W(I) \times W(J) \tag{1}$$

(3) Tongue/face region recognition

The face and tongue regions must be recognized before extracting TCM syndrome features from tongue and face images. This paper calls the Dlib face detector, which contains a trained face key point detector, and a trained face recognition model.

The face alignment algorithm based on regression tree was adopted to gradually restore the real face shape by setting up a cascaded residual regression tree. In each residual regression tree, every leaf node stores a residual regression quantity. When the input reaches a node, it is modified by adding the residual, serving the purpose of regression. When all residual errors are added together, the human face is fully restored [23] (Figure 6).

Then, you only look once (YOLO) algorithm was employed to identify the body and moss of the tongue. YOLO relies on a single neural network to realize end-to-end detection of targets. As shown in Figure 7, the input image is resized to 448×448. Then, the resized image is sent to the convolutional neural network (CNN). Finally, the prediction results are processed through non-maximum suppression (NMS), generating the detected target.

Figure 6. Recognized face area

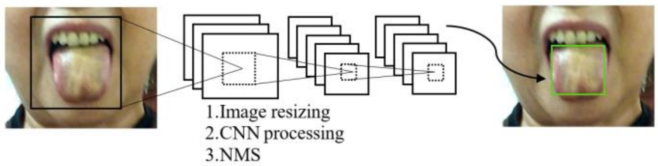


Figure 7. Recognition of the body and moss of the tongue

(4) Tongue/face color extraction

Each pixel in the recognized face area has a unique red-green-blue (RGB) value. To express the redness more intuitively, RGB values were converted into hue-saturation-value (HSV) values.

Firstly, R, G, B values were divided by 255 to change the range from [0, 255] to [0, 1]:

$$R' = R/255 \tag{2}$$

$$G' = G/255 \tag{3}$$

$$B' = B/255 \tag{4}$$

$$C_{max} = max(R', G', B') \tag{5}$$

$$C_{min} = min(R', G', B') \tag{6}$$

$$\Delta = C_{max} - C_{min} \tag{7}$$

Then, the H, S, and V values were respectively calculated by:

$$H = \begin{cases} 0^{\circ} & \Delta = 0 \\ 60^{\circ} \times \left(\frac{G' - B'}{\Delta} mod6\right), & C_{max} = R' \\ 60^{\circ} \times \left(\frac{B' - '}{\Delta} + 2\right), & C_{max} = G' \\ 60^{\circ} \times \left(\frac{R' - G'}{\Delta} + 4\right), & C_{max} = B' \end{cases} \tag{8}$$

$$S = \begin{cases} 0, & C_{max} = 0 \\ \dfrac{\Delta}{C_{max}}, & C_{max} = 0 \end{cases} \quad (9)$$

$$V = C_{max} \quad (10)$$

According to our early investigation on 200 PHDS-induced insomnia patients in five large tertiary hospitals, the H values of tongue redness and face redness fell in 39°-91° and 25°-93°, respectively. Thus, the tongue redness could be calculated by dividing the number of pixels in the tongue redness range with the number of pixels of the tongue body. Similarly, the face redness could be solved by divided the number of pixels in the face redness range with the number of face pixels.

(5) Moss thickness extraction

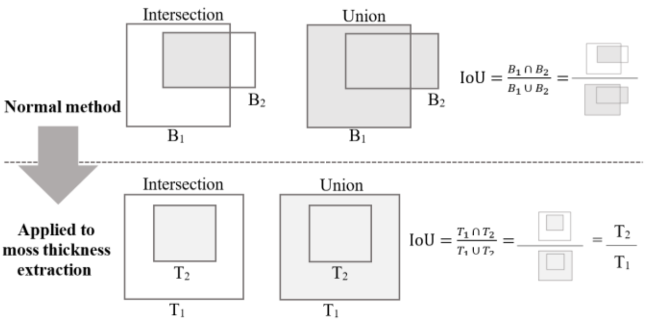


Figure 8. Moss thickness extraction based on intersection over unition (IoU)

This paper couples YOLO, which is suitable for moss thickness detection, with IoU target detection algorithm to calculate the proportion of moss to tongue body, and thus derive the feature of moss thickness. The IoU-based feature extraction process is illustrated in Figure 8.

Through the above steps, this paper extracts features like tongue color, moss thickness, and face color from tongue and face images. The values of these features range between zero and one.

(6) Efficacy analysis based on multi-modal data fusion

Multi-modal features can be fused by various methods. Feature addition stands out for its high accuracy [24]. Chu et al. [25] proposed a multi-modal feature fusion method based on weight distribution, and demonstrated that the method significantly outperforms single feature fusion. In addition to the extracted features like tongue color, moss thickness, and face color, PSQI score (rang: 0-21) and sleep structure score (range: 0-100) were adopted to indicate sleep quality. The two eigenvalues were normalized by dividing with the maximum. Finally, feature addition was adopted to fuse the characteristic weights and normalized eigenvalues obtained by the Delphi method:

$$F = \sum f_i W_i \quad (11)$$

where, F is the score of insomnia severity; f_i is the quantization value of each feature; W_i is the weight of each feature. Comparing the insomnia severity scores before and after treatment, the variation of insomnia severity, that is, the treatment efficacy (TE) was obtained. If $TE = F_{after} - F_{before} < 0$, insomnia is alleviated; if $TE = F_{after} - F_{before} > 0$, insomnia is worsened. The greater the absolute value of TE, the more significant the variation in insomnia severity, and the more impactful the treatment.

4. RESULTS

From the perspective of the user, the HEMIES must be sufficiently accurate in actual use. Therefore, the HEMIES was tested through treatment efficacy evaluation of TCM syndrome images and modern medicine text data, which were collected from patients with HDPF-induced insomnia before and after the treatment. The evaluation results of the system were compared with the diagnosis by clinical doctors in hospitals to verify the accuracy of HEMIES.

4.1 Experimental design

Thirty-three patients with primary HDPF-induced insomnia were observed for three months to reveal the treatment efficacy of insomnia. Each patient used a self-developed wearable TEST instrument for home treatment (Figure 9). Before and after the treatment, every subject fed back multi-modal data for the system to predict treatment efficacy. Table 3 explains the home treatment approach for the HDPF-induced insomnia.

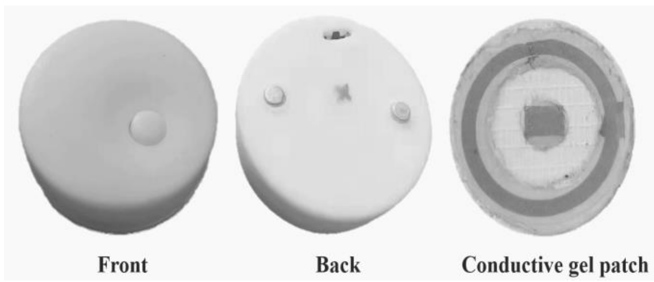
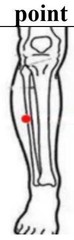


Figure 9. The self-developed wearable TEST instrument

Table 3. Home treatment approach for the HDPF-induced insomnia

Syndrome	Sample size	Primary acupuncture point	Secondary acupuncture point	Methodology
HDPF	33	 Shen Men	 Feng Long	Noninvasive electrical stimulation treatment (30 mins/time/day) with the self-developed wearable TEST instrument; the intensity of electrical stimulation can be adjusted independently by the patient. The treatment frequency is 6 times per week. Each course of treatment lasts 4 weeks. Three consecutive courses are required.

4.2 Results of expert evaluation

The pre- and post-treatment TCM syndrome images and modern medicine text data of the patients were emailed to 15 experts on before and after treatment. The treatment efficacy evaluated by these experts is displayed in Table 4.

4.3 HEMIES prediction of the first experiment

Figure 10 shows the pre- and post-treatment insomnia severity of the 33 patients predicted by the HEMIES.

Taking the first and the third patients for example, $F_{before1} = 0.67$; $F_{after1} = 0.30$; $TE_1 = F_{after1} - F_{before1} = -0.37$; $F_{before3} = 0.65$; $F_{after3} = 0.36$; $TE_3 = F_{after3} - F_{before3} = -0.29$. The insomnia severity of the two patients was relieved through the treatment, i.e., the treatment is effective on both patients. Since $|TE_1|$=0.37 and $|TE_2|$=0.29, their insomnia severity changed by 0.36 and 0.29, respectively. Therefore, the treatment effect was better on the first patient than on the third patient.

Table 4. Results of expert evaluation

	Better	Worse
Serial number	1; 3; 4; 5; 6; 7; 8; 9; 10; 13; 15; 16; 17; 18; 19; 20; 21; 22; 23; 24; 25; 26; 27; 28; 29; 30; 32; 33	2; 11; 12; 14; 31
Sum	28	5

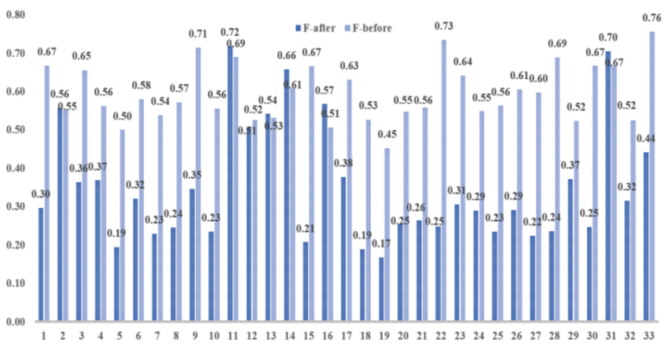


Figure 10. Pre- and post-treatment insomnia severity

Next, system predictions were compared with expert evaluations to produce a confusion matrix of treatment efficacy prediction. Because the distribution of the two results is not balanced in the test samples, precision was adopted to measure the prediction ability of our system. As shown in Figure 11, HEMIES achieved a good prediction effect, with an accuracy as high as 87.88%.

Figure 11. Confusion matrix of treatment efficacy prediction
Note: The abscissa is the predicted value; the ordinate is the true value.

4.4 HEMIES prediction of the second experiment

The problem with the first experiment is the failure to consider the beautification and filtering effects of the camera. During the quality check of the tongue and face images, it was discovered that the post-treatment images of the thirteenth patient are beautified by the red filter of the camera (Figure 12), which highlights the redness of the tongue and face. This clearly undermines the accuracy of system prediction.

Therefore, a second experiment was carried out after eliminating the thirteenth patient. The predicted results of HEMIES are shown in Figure 13. The confusion matrix obtained from the second experiment is shown in Figure 14. It can be seen that the accuracy of HEMIES prediction rose to 90.63%, after eliminating the impact of beautification.

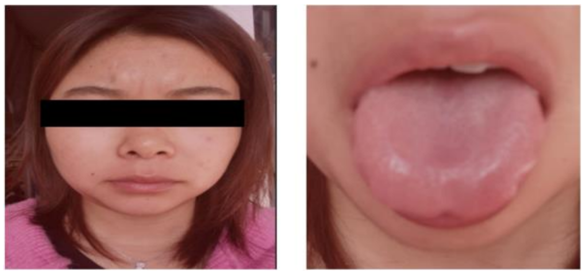


Figure 12. Beautified image of the thirteenth patient (ambient light: reddish)

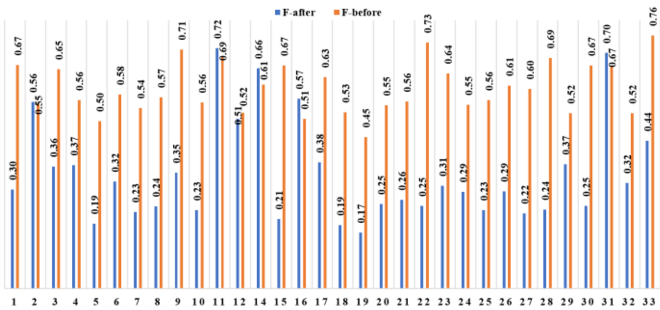


Figure 13. Predicted results of the second experiment

Figure 14. Confusion matrix of the second experiment

5. DISCUSSION

In the first experiment, the HEMIES correctly predicted 25 patients as getting better, and 4 patients as getting worse. In total, 29 patients were correctly predicted. Meanwhile, our system incorrectly predicted 2 patients as getting better, and 2 patient as getting worse. That is, 4 patients were incorrectly predicted. Overall, the accuracy rate of HEMIES prediction was 87.88%.

In the second experiment, after excluding the patient whose images are collected under nonstandard conditions, the HEMIES correctly predicted 25 patients as getting better, and 4 patients as getting worse. In total, 29 patients were correctly predicted. Meanwhile, our system incorrectly predicted 2 patients as getting better, and 1 patient as getting worse. That is, 3 patients were incorrectly predicted. Overall, the accuracy rate of HEMIES prediction was 90.63%.

The above two experiments demonstrate the good prediction effect of the HEMIES on the treatment efficacy of wearable TEST instrument in HDPF-induced insomnia, indicating that the system can be applied to evaluate home treatment. However, the quality of the tongue and face images could be affected by various factors in the home environment, namely, the ambient light source, the shooting angle, the user's beautification habit, etc. Any disturbance from such factors would drag down the prediction accuracy of the system. To ensure the prediction effect of HEMIES, the user is recommended to face the camera indoors at 10 am, use a high-resolution cellphone, and turn off the beautification function before taking images of his/her tongue and face. In future, our research team will develop a portable device to capture standardized tongue and face images, aiming to improve the accuracy of system prediction. Another limitation of this research lies in the limited size of the test samples. All the patients were from a tertiary hospital in Hangzhou, China, lacking regional diversity. The future research will collect more and diverse samples from various places to verify the accuracy of the HEMIES.

6. CONCLUSIONS

Taking HDPF-induced insomnia as an example, this paper develops a novel HEMIES to objectively evaluate the treatment efficacy of wearable TCM treatment equipment in the home treatment of diseases. After reviewing the literature, an index system was established for the HEMIES on HDPF-induced insomnia, each index was assigned a weight by the Delphi's method, and a conceptual model was developed for the HEMIES. Next, target detection and image analysis algorithms were called to extract the features of the tongue and face objectively. Then, TCM syndrome images were merged with modern medicine text data to evaluate the treatment efficacy, and complete the design of the HEMIES. Finally, the prediction accuracy of the HEMIES was evaluated through treatment efficacy evaluation experiments. The experimental results show that, excluding the image of a patient distorted by the beautification function of the camera, the HEMIES achieved an extraordinary accuracy of 90.63%, a sign of excellent prediction ability. The HEMIES provides a tool to objectively evaluate the efficacy of wearable TEST instruments in home treatment of HDPF-induced insomnia, i.e., in the absence of TCM practitioners. The research provides a reference for the efficacy evaluation of various wearable TCM treatment devices in home treatment of other diseases.

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