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# The Application of the Complementary and Alternative Therapies in Relieving Insomnia for Cancer Patients

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## Abstract

**Objective:** To observe the curative effect of the complementary and alternative therapies in relieving insomnia for cancer patients.

**Method:** According to the principle of randomization, with meeting the inclusion criteria, the 60 patients who were diagnosed as insomnia caused by liver qi stagnation were randomly divided into the control group and the intervention group. The intervention group (30 individuals treated with mini-needle therapy combined with TCM five elements music), the control group (30 individuals who were treated with single mini-needle therapy), the body buried needle 24 hours/time, 5 times for a course of treatment, interval of 2 days between 2 courses, a total of 8 needles embedded. Pittsburgh sleep quality index (PSQI) scores of 2 groups were analyzed using SPSS19.0 statistical software.

**Results:** The total effective rate was 86.1% in the intervention group, and 75.9% in the control group, the difference was statistically significant between 2 groups ( $P < 0.05$ ). The comparison of the PSQI score between the 2 groups pre-post treatment showed that there were statistically significant differences ( $P < 0.05$ ). The reduction rate of PSQI in the intervention group was 31.7%, indicating that 31.7% was effective, while 23.1% in the control group was ineffective.

**Conclusion:** The mini-needle therapy combined with TCM five elements music could relieve insomnia caused by qi stagnation of liver in patients with advanced cancer.

**Key words:** TCM five elements music; Mini-acupuncture; Insomnia; Qi stagnation of liver; Advanced cancer

## Introduction

Malignant tumors have become relatively frequent and

common diseases<sup>[1]</sup>. And Insomnia has become one of the serious problems for such patients undergoing chemotherapy, accounting for 54.72% of the total incidence of insomnia, which often has an impact on patients' mental health<sup>[2]</sup>, with an incidence of higher than 70%<sup>[3]</sup>. Insomnia is a common clinical disease,

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seriously affecting the rehabilitation of patients, for which an adequate sleep is necessary to help rehabilitation<sup>[4]</sup>. Music therapy as an important part of psychological interventions<sup>[5]</sup>, can ensure patients' sleep quality<sup>[6-7]</sup>. Mini-needle therapy is the development of acupuncture needles (it can be extended to the whole role of acupuncture), which is used to improve clinical efficacy, and is widely used in clinical procedures<sup>[8]</sup>. Traditional Chinese medicine (TCM) believes that insomnia is classified with in the "disorders" category, for which there are several treatment methods. In this study, 60 cases of advanced cancer patients were treated with mini-needle therapy to improve the patient's insomnia symptoms, and a half of the patients (the intervention group) were treated with addition of TCM five elements music. The results showed that the intervention group achieved beneficial effects.

## Materials and Methods

### *Ethic committee*

This study was approved by ethic committee of Xiyuan Hospital, China Academy of Chinese Medical Sciences.

### *Inclusion criteria*

(1) Patients with stable vital signs and clear consciousness; (2) Patients were diagnosed with malignant tumors; (3) Patients had insomnia for more than 4 weeks, and did not take psychiatric drugs or had stopped taking more than 2 weeks; (4) Before treatment, patients could accept this fact, were willing to participate in this test, and signed the informed consents; (5) Patients were not accompanied by other serious physical illness; (6) Patients had no mental disorders, and could independently complete the questionnaire survey before and after chemotherapy. (7) Diagnostic criteria of insomnia in line with *Chinese Psychiatric Classification and Diagnostic Criteria* (3rd edition) (CCDM-3)<sup>[9]</sup> in the diagnosis of insomnia, and liver insomnia in line with the diagnostic criteria of *Internal Medicine of Traditional Chinese Medicine*<sup>[10]</sup>.

### *Exclusion criteria*

Patients with any one of the following were excluded: (1) Other causes or other diseases caused insomnia; (2) Patients with primary diseases of heart, liver, kidney,

brain and other organs; (3) Patients with disturbance of consciousness, language communication disorders and poor degree of poor patients; (4) Patients with mental drug abuse or dependence; (5) Patients had nearly 1-week history of fever and infection. (6) Patients couldn't cooperate with the treatment.

### *Patients*

Totally 60 cases of advanced cancer patients admitted to the oncology department of Xi Yuan Hospital, China academy of Chinese Medical Sciences from July 2016 to August 2017 were selected and diagnosed as hepatic qi stagnation type insomnia. All patients had definite history of insomnia. And because of voluntary withdrawal of 1 patient, and termination of aggravation of 1 patient, 58 cases were included ultimately, including 23 male and 35 female. According to the international TNM staging standard (UICC), there were 1 case of stage II, 1 case of stage III, 1 case of stage IIIB, and 55 cases of stage IV. The diagnosis of cancer included 12 cases of breast cancer, 14 cases of lung cancer, 9 cases of rectal cancer, 5 cases of colon cancer, 1 case of pancreatic cancer, 2 cases of ovarian cancer, 2 cases of gastric cancer and 13 cases of other diseases.

The SAS software generated random number. According to the patient into the order of random access, and distribution ratio (1:1), the 58 patients were randomly divided into control group (n=29) and intervention group (n=29). The intervention group received intradermal buried needle (mini-needle acupuncture) combined with TCM five elements music, and the control group received intradermal buried needle alone. The intervention group had 12 males and 17 females, aged 36-70 years old, while the control group had 11 males and 18 females, aged 36-71 years old. There was no statistically significant difference in the distribution of baseline data such as age, gender, and tumor stage between the 2 groups ( $P>0.05$ ).

### *Treatment*

**Control group:** 0.20 mm × 1.5 mm one-time sterilization of SEIRIN Co., Ltd. The selected acupoints were Xinshu, Shenshu, Ganshu, Shenmen, Neiguan, Zusanli, Sanyinjiao, Baihui, Yintang, Shendao, Zhaohai, Taichong,

and Yongquan under the guidance of the syndrome differentiation. After the sterile disposable mini-needle is inserted into the selected acupoint, press the needle and paste it well. The mini-needle has to be buried for 48 hours; Acupoints should be pressed 4 times a day for 1 minute each time, with an interval of 4 hours. Pressure intensity is based on the patient's tolerance.

**Intervention group:** On the basis of single mini-needle therapy, TCM five elements music therapy was supplemented for the treatment of liver qi stagnation. And melodic music with Yu tone (one of five-tone scale in TCM) and Jiao-tone (one of five-tone scale in TCM) were used, 30 minutes/time, 15 minutes for each style of music, 5 times for each course of treatment, 4 courses in total. The interval of 2 days was appropriate between 2 courses. All of the above operations are carried out after standardized training.

#### **Observational indicators**

Pittsburgh Sleep Quality Index (PSQI) table was used to assess the sleep quality of patients of 2 groups before and after treatment<sup>[6]</sup>. The table consists of 18 entries composed of 7 factors, each factor scores ranging from 0 to 3 points. The total score is 0 to 21 points. The higher the scores were, the worse the sleep quality was. There was no assessment of insomnia drugs in the PSQI scale because the intervention group did not use sedative drugs. Before treatment, the patients were observed and recorded. After 4 courses of treatment, they were observed and recorded again.

The standard of efficacy with reference to clinical efficacy criteria of *Chinese Medicine New Drug Clinical Research Guidelines* promulgated by the Ministry of Health in 1993<sup>[7]</sup>. Reduction rate of PSQI score = [(Score before

treatment - Score after treatment)/Pre-treatment score] × 100%, including (1) recovery: PSQI reduction rate up to 76%-100%, (2) markedly: PSQI reduction rate up to 51%-75%; (3) effective: PSQI reduction rate up to 25%-50%, and (4) invalid: PSQI reduction rate <25%.

#### **Statistical analysis**

SPSS 21.0 statistical software to analyze the data, all data are used bilateral test, the enumeration data was described by percentages (%), the measurement data was described by the mean and standard deviation ( $\bar{x} \pm s$ ). The comparison of repeated measurement data within the group was conducted using repeated measurement ANOVA, and the comparison between groups using *t* test, variance Analysis or rank sum test.  $P < 0.05$  was considered statistically significant.

## **Results**

#### **The comparison of efficacy between both groups**

the total effective rate was 86.1% in the intervention group, and 75.9% in the control group. The efficacy of the 2 groups was compared using the rank of test, the difference was statistically significant ( $P < 0.05$ ), suggesting that the intervention group was better than the control group. (Table 1)

#### **The comparison of the reduction rate of PSQI score between the 2 groups**

The comparison of the PSQI score between the 2 groups pre-post treatment showed that there were statistically significant differences ( $P < 0.05$ ). The reduction rate of PSQI score in the intervention group was 31.7%, indicating that 31.7% was effective, while 23.1% in the control group was ineffective. (Table 2)

**Table 1 The comparison of efficacy between both groups**

Groups	Cases	No effect	Effect observed	Remarkable effect	Full recovery	Total effective rate (%)
Intervention group	29	4(13.8%)	7(24.1%)	17(58.6%)	1(3.4%)	86.1
Control group	29	7(24.1%)	10(34.5%)	12(41.4%)	0	75.9

**Table 2 The comparison of the reduction rate of PSQI score between the 2 groups ( $\bar{x} \pm s$ )**

Groups	Case	Treatment	Total PSQI (points)	Reduction of PSQI score (points)	Reduction rate (%)
Intervention group	29	Pro-T	18.36±2.41	5.82±1.62	31.7
		Post-T	12.54±3.54		
Control group	29	Pro-T	17.97±2.67	4.14±1.04	23.1
		Post-T	13.82±1.97		

**Notes:** Pro-T refers to pro-treatment; Post-T refers to post-treatment

**Table 3 The comparison of the total PSQI score pro-post treatment within each group ( $\bar{x} \pm s$ ) points**

Groups	Baseline	2 weeks after treatment	4 weeks after treatment	F	P
Intervention group	18.36±2.41	13.67±2.41	12.54±2.41 <sup>##</sup>	23.143	0.027
Control group	17.97±2.67	14.11±2.67	13.82±2.67 <sup>*</sup>	21.684	0.051
F	1.211	6.737	19.237		
P	0.722	0.083	0.001		

<sup>##</sup>P<0.05

### **Comparison of the total PSQI score pro-post treatment within each group**

The repeated measurement ANOVA was used for the intra-group measurement. It was shown that there were statistically significant differences pro-post treatment within each group ( $P<0.05$ ). At the same time, there was significantly differences of the total PSQI score 4 weeks after treatment when comparing the 2 groups ( $P<0.05$ ). (Table 3)

## **Discussion**

Insomnia is also known as wakefulness, which is mainly due to various causes of the body caused by imbalance between yin and yang. According to TCM syndrome differentiation, insomnia can be divided into 5 types, including qi stagnation of liver type, yin deficiency with fire hyperactivity type, heart and spleen deficiency type, qi deficiency of heart and gallbladder type, and phlegm-heat obstruction in the lung. The focus of this study is concerned with insomnia. Patients mainly manifested as difficult to sleep, irritability, bitter and dry mouth, *etc.*, the pathogenesis of emotional disorders lead to liver catharsis, stagnant fire damaging the spirit. In addition to insomnia patients, also, insomnia leads to a series of clinical

symptoms such as chest distress, headache, constipation, urine and other clinical symptoms. Long-term insomnia makes patients miserable, which further increases the psychological problems.

With the comprehensive advancement of China's health care reform, and the emphasis on TCM inheritance and development, the use of needle in the clinical research has been gradually deepened, and has unique advantages in improving the subjective symptoms. As a new type of modified needle, it is easy to operate, and the human body does not produce side effects similar to drugs when medical staff press the needle. As an effective TCM technology, it has been widely used in clinical practice<sup>[11-14]</sup>. Gao *et al.*'s study<sup>[15]</sup> shows that auricular acupressure has its unique advantages in improving sleep disorders and patient's daytime functional status adjustment. Li *et al.*<sup>[12]</sup> reported a clinical study of the use of mini-needle therapy with rehabilitation guidelines for the treatment of knee osteoarthritis, to verify clinical efficacy of the treatment of knee osteoarthritis, and the results showed that it can be a good relief of knee pain, and a good method to improve the knee function; Shi *et al.*<sup>[16]</sup> summed up the clinical study of the role for

acupuncture therapy in pain syndrome, once again verified that acupuncture could promote qi and blood circulation, and pressing the needle and continued needle-embedding in the skin or subcutaneously could give a specific acupoints to long-lasting and gently benign stimulation, thereby enhancing the efficacy of acupuncture analgesia, and playing to prevent the recurrence of pain. As part of the psychological intervention, Chinese medicine has played an important complementary role in clinical treatment, and several studies<sup>[6, 17-18]</sup> have confirmed that music therapy can improve sleep quality. Besides having a direct impact on mood states, music therapy can have physiological effects. The mechanism is based on the auditory system and the role of the cerebral cortex, which can stimulate the body to promote physical and mental health<sup>[19]</sup>. Studies have confirmed that music therapy can improve sleep quality, increase parasympathetic activity, and regulate muscle tension and blood flow<sup>[20]</sup>. According to the theory of the TCM five elements, for hepatic qi stagnation type insomnia, the Jiao-tone music (one of five-tone scale in TCM, the equivalent of “3-mi”, the third note in a musical scale according to the sol-fa system), is selected as the main tones, corresponding to wood (one of the five elements), and into the liver and gallbladder, with the functions of dispersing stagnated liver qi to relieve depression, tonifying the heart and spleen, clearing liver-fire, and soothing the nerves. At the same time, according to the principle of “Mother-supplementing”, Yu-tone music (one of five-tone scale in TCM) is chosen to strengthen the kidney function, nourish the kidney yin, liver and heart, and purge the liver fire. The Yu-style music (the equivalent of 6-la) was as the main tones, corresponding to water (one of the five elements), into the kidney.

Western medicine for the intervention of insomnia is to allow patients to take anti-anxiety agents and sedative hypnotic drugs to achieve the goal of alleviating insomnia, but most of the drugs will have a normal impact on the body's normal sleep structure, resulting in clinical symptoms of patients' attention unable to focus during the day, while anti-anxiety agents and sedative hypnotic drugs addiction and withdrawal reactions severely limit the clinical use of these drugs<sup>[9]</sup>.

In this study, It was shown that there were statistically significant differences pro-post treatment within each group ( $P < 0.05$ ). At the same time, there was significantly differences of the total PSQI score 4 weeks after treatment when comparing the 2 groups ( $P < 0.05$ ). In this study, we used the mini-needles to effectively stimulate human body acupuncture points to nourish nerve, promote the blood circulation, for pressing the needle buried in the skin continuously and fixedly can give specific acupoints with durable, soft benign stimulation to treat disease<sup>[21-22]</sup>.

At the same time, in this study, patients in the intervention group used to listen to TCM music, music therapists through the principle of music therapy, “induced”, “suggested”, “supported”, and “showed empathy”, and used other ways to lead patients to produce a variety of psychological experience. when listening to five-element music, the sweet music can stimulate the ear canals, through which the sensation is then deliver to the special area in human brain based on the physiological resonance, to achieve the purpose of improving insomnia.

In summary, the skin buried needle technology combined with the TCM five elements music can improve the quality of life of patients with advanced liver cancer who suffer from liver qi stagnation. Additionally, this practice does not cause dependency, and it is an economical and practical method to relieve mood states.

## Declaration

The authors of this article declare that they have no conflict of interest.

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