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**Special Topic for 973 Program**

# Effect of mild-warm moxibustion on fatigue, immune state and quality of life in sub-health population

## 温和灸对亚健康人群疲劳、免疫状态及生存质量的影响

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**Abstract**

**Objective:** To observe the effect of mild-warm moxa stick moxibustion on fatigue, immune state and quality of life (QOL) in sub-health population.

**Methods:** A total of 120 cases were randomly allocated into a moxibustion group ($n$=60) and a Chinese patent medicine (CPM) group ($n$=60). People in the moxibustion group were intervened with mild-warm moxa stick moxibustion, once a day; while people in the control group took oral *Bu Zhong Yi Qi Wan* (Spleen/stomach-supplementing and Qi-boosting Pill), 3 doses a day. Two months made up a course of treatment. The fatigue, immune state and QOL were then observed after one treatment course, followed by a 12-month follow-up.

**Results:** A total of 115 cases completed the clinical trial. After intervention, the fatigue scores, immune parameters and QOL scores were significantly increased in both groups, showing statistical significances ($P$<0.05). There were between-group significant differences in fatigue score, levels of immunoglobulin M (IgM) and IgG, natural killer (NK) cell activity and QOL score ($P$<0.05). After the 12-month follow-up, there were still significant between-group differences in fatigue score, physical health, psychological, social relationships and overall perception of QOL and overall perception of health ($P$<0.05).

**Conclusion:** Mild-warm moxibustion can markedly improve the fatigue, immune state and QOL in sub-health population.

**Keywords:** Moxibustion Therapy; Moxa Stick Moxibustion; Fatigue; Quality of Life; Immunoglobulins

**【摘要】目的：**探讨艾条温和灸对疲劳性亚健康人群疲劳、免疫状态及生存质量的影响。**方法：**将 120 例患者按照就诊顺序随机分为艾灸组和中药组，每组 60 例。艾灸组采用艾条温和灸干预，1 次/d，中药组给予补中益气丸口服，3 次/d，连续治疗 2 个月为 1 个疗程。两组均在治疗 1 疗程后观察患者疲劳、免疫状态及生存质量，并随访 12 个月。**结果：**共 115 例患者完成了临床试验，两组患者治疗后疲劳评分、免疫学指标及生存质量评分与治疗前比较均显著改善，差异均有统计学意义($P$＜0.05)。艾灸组患者治疗后疲劳评分，免疫球蛋白 M (immunoglobulin M, IgM)、IgG 含量及自然杀伤 (natural killer, NK)细胞活性，生存质量评分与中药组差异比均有统计学意义($P$＜0.05)。12 个月随访结束时艾灸组患者疲劳评分及生理、心理、社会关系、生存质量主观感觉、健康状况主观感觉评分与中药组均有统计学差异($P$＜0.05)。**结论：**温和灸可明显改善疲劳性亚健康人群的疲劳症状、免疫状态与生活质量。

**【关键词】**灸法；艾条灸；疲劳；生存质量；免疫球蛋白

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Sub-health (also known as suboptimal health status) has now become a major threat to human health. It's of great urgency to prevent and manage sub-health[1-2]. Although there is no such term as 'sub-health' in Chinese medicine, the concept of '*wei bing*' (literally meaning health problems before onset) was mentioned in the *Huang Di Nei Jing* (*Yellow Emperor's Classic of Internal Medicine*). With its long history and unique efficacy, moxibustion can be a research priority in sub-health intervention[3-4]. The purpose of this study was to observe changes in fatigue, immune state and quality of life (QOL) in sub-health population before and after moxibustion, explore the effect of mild-warm moxibustion and lay a foundation for further sub-health intervention with moxibustion.

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## 1 Clinical Materials

### 1.1 Diagnostic criteria

This was based on the diagnostic criteria in *Clinical Guidelines of Chinese Medicine on Sub-health* issued by the China Association of Chinese Medicine: Prolonged fatigue for at least 3 consecutive months or fatigue that cannot be relieved by rest but does affect normal work; not a result of mental or other medical conditions; fatigue self-assessment scale (FSAS) score[5] ≥3 points.

### 1.2 Inclusion criteria

Those who met the above diagnostic criteria for sub-health status; no gender limit; aged between 25 and 55; having at least junior middle school educational; and having signed the informed consent.

### 1.3 Exclusion criteria

Those who didn't meet the above diagnostic and inclusion criteria; having severe primary conditions in cardio-cerebral, liver, kidney, hemopoietic, endocrine and immune systems; having mental disorders; having severe diabetes or tumor; pregnant or breast-feeding women; having taken medication or other therapies during the study that may affect efficacy evaluation; and those who refused to sign the informed consent.

### 1.4 Termination criteria

Sudden onset of other medical conditions that may affect efficacy and safety evaluation; failure to continue due to severe adverse reactions; and trial subjects were unwilling to continue.

### 1.5 Statistical management

The SPSS 17.0 version software was used for data analysis. The measurement data were expressed in the form of mean ± standard deviation ($\bar{x} \pm s$). The paired *t*-test (intra-group comparison) and independent-samples *t*-test (inter-group comparison) were used for measurement data in normal distribution and equal variances. The nonparametric test was used for measurement data in non-normal distribution and unequal variances. The Chi-square test was used for enumeration data. A *P* value of less than 0.05 indicated a statistical significance.

### 1.6 Research subjects

A total of 120 cases who complained of fatigue in Medical Examination Centers and Acupuncture Departments of Anhui Provincial Hospital of Traditional Chinese Medicine and Anhui Provincial Hospital of Acupuncture-moxibustion between January 2012 and June 2013 were selected as the trial subjects. They all had prolonged or recurrent fatigue for at least 3 consecutive months, met the inclusion and exclusion criteria, and signed the informed consent. They were randomly allocated into a moxibustion group ($n$=60) and a Chinese patent medicine (CPM) group ($n$=60). There were no significant between-group differences in gender, age and duration ($P$>0.05), indicating that the two groups were comparable (Table 1).

A total of 115 cases completed the clinical trial: 1 case in the moxibustion group discontinued because of a bad cold and 1 case dropped out of the trial; 1 case in the CPM group discontinued because of business trips and another 2 cases dropped out of the trial (Figure 1).

**Table 1. Between-group comparison in baseline data**

| Group | $n$ | Gender (case) | | Mean age ($\bar{x} \pm s$, year) | Mean duration ($\bar{x} \pm s$, month) |
|---|---|---|---|---|---|
| | | Male | Female | | |
| Moxibustion | 58 | 35 | 23 | 47.6±9.5 | 10.1±1.8 |
| CPM | 57 | 34 | 23 | 46.8±9.1 | 9.3±1.7 |

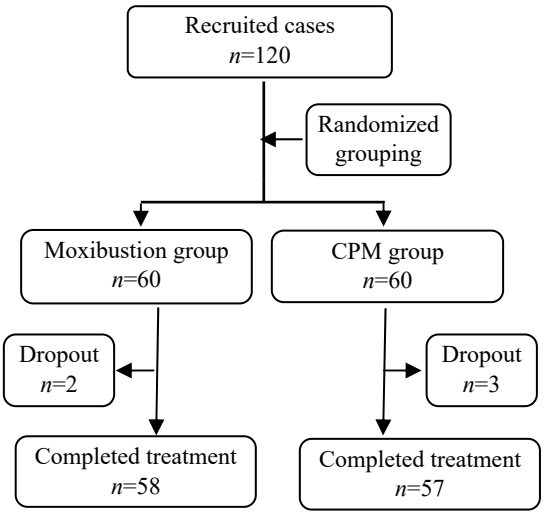


**Figure 1. The flowchart**

## 2 Treatment Methods

### 2.1 Moxibustion group

Points: Qihai (CV 6), Zhongwan (CV 12), Guanyuan (CV 4) and bilateral Tianshu (ST 25), Sanyinjiao (SP 6) and Zusanli (ST 36).

Method: Moxa sticks of 18 mm in dimeter and 200 mm in length (Nanyang Wolong Hanyi Moxa Factory, China) were used for mild-warm moxibustion. The patients took a supine lying position to fully expose the abdomen and lower limbs. The practitioner ignited the moxa stick and placed 2-3 cm away from the skin around the points until a mild warm (rather than burning hot) sensation occurred. The moxibustion was done about 10 min for each point (until the local skin became red), once a day. A total of 2 consecutive months made up a course of treatment.

### 2.2 CPM group

Subjects in this group took 6 g *Bu Zhong Yi Qi Wan* (Spleen/stomach-supplementing and Qi-boosting Pill, approval number: 11020244, Pharmaceutical Factory of

Beijing Tongrentang Science & Technology Corporation, China) for each dose, 3 doses a day, for a total of 2 months.

The efficacies in both groups were observed after a course of treatment. During the treatment, subjects were told to stay optimistic, have regular lifestyles and avoid fatigue.

## 3 Results Observation

### 3.1 Observation parameters

3.1.1 FSAS

FSAS, including 23 items, was used to assess the category, severity and characteristics of fatigue as well as intervention effect. The scale had two parts. The first part was about the fatigue category and severity, including mental fatigue, physical fatigue and consequences of fatigue. The second part was about the characteristics of fatigue, including the situation specificity of fatigue and responsiveness of fatigue to sleep.

3.1.2 Immune items

The levels of immunoglobulin A (IgA), IgG and IgM and natural killer (NK) cell activities in subjects were measured before and after treatment.

3.1.3 Assessment on QOL

The World Health Organization quality of life-brief, WHOQOL-brief)[6] was used to assess the patients' QOL, including 6 domains: the overall perception of QOL, overall perception of health, physical health, psychological, social relationships and environment. Each item in the first two domains is scored from 0 to 5 points. The last four domains consist of 24 questions. Domain scores are scaled in a positive direction (i.e. higher scores denote higher QOL).

3.1.4 Follow-up observation

The follow-up visit was made 12 months after treatment to compare the fatigue and QOL scores in the two groups.

### 3.2 Results

There were no reports of adverse reactions in either group during the treatment.

3.2.1 Between-group comparison in FSAS score

After treatment, the fatigue scores in both groups were significantly decreased, showing statistical significances ($P<0.05$); and significant between-group differences in physical fatigue, mental fatigue, consequences of fatigue, and responsiveness of fatigue to sleep ($P<0.05$). The follow-up visit 12 months after treatment showed significant between-group differences except for situation specificity of fatigue ($P<0.05$). This indicated that mild-warm moxibustion could significantly improve fatigue scores in sub-health population and had a long-term effect (Table 2).

3.2.2 Between-group comparison in immune state

After treatment, the levels of IgA, IgM and IgG as well as NK cell activity were elevated in both groups, showing statistical significances ($P < 0.05$); and significant between-group differences in levels of IgM and IgG as well as NK cell activity ($P<0.05$). This indicated that mild-warm moxibustion could boost the immune function in sub-health population (Table 3).

**Table 2. Comparison in FSAS score ( $\bar{x}$ ±*s*, point)**

| Group | *n* | Time | Mental fatigue | Physical fatigue | Consequences of fatigue | Responsiveness of fatigue to sleep | Situation specificity of fatigue |
|---|---|---|---|---|---|---|---|
| Moxibustion | 58 | Before treatment | 28.6±3.5 | 36.8±4.8 | 27.5±3.1 | 65.1±7.8 | 52.6±7.1 |
| | | After treatment | 12.1±2.0[1)2)] | 11.5±2.3[1)2)] | 9.5±1.4[1)2)] | 20.3±3.1[1)2)] | 38.6±5.6[1)] |
| | | Follow-up visit | 14.2±2.1[2)] | 12.8±2.2[2)] | 11.2±1.8[2)] | 24.3±3.9[2)] | 42.2±6.8 |
| CPM | 57 | Before treatment | 29.1±4.1 | 36.3±4.8 | 28.1±4.1 | 62.5±8.3 | 52.8±7.9 |
| | | After treatment | 20.1±2.6[1)] | 28.3±3.1[1)] | 19.3±2.9[1)] | 32.2±4.7[1)] | 42.3±6.2[1)] |
| | | Follow-up visit | 23.5±3.1 | 22.3±4.2 | 20.3±3.3 | 36.6±4.5 | 45.6±6.9 |

Note: The intra-group comparison before and after treatment, 1) $P<0.05$; the same time between-group comparison, 2) $P<0.05$

**Table 3. Comparison in immunological parameters ( $\bar{x}$ ±*s*)**

| Group | *n* | Time | IgA (g/L) | IgG (g/L) | IgM (g/L) | NK (%) |
|---|---|---|---|---|---|---|
| Moxibustion | 58 | Before treatment | 1.39±0.15 | 7.71±0.92 | 0.71±0.11 | 26.82±3.8 |
| | | After treatment | 1.51±0.18[1)] | 11.28±1.54[1)2)] | 1.62±0.28[1)2)] | 44.57±6.7[1)2)] |
| CPM | 57 | Before treatment | 1.38±0.11 | 7.75±0.88 | 0.68±0.12 | 27.31±4.1 |
| | | After treatment | 1.46±0.20 | 9.07±1.39[1)] | 1.49±0.30[1)] | 37.41±5.3[1)] |

Note: The intra-group comparison before and after treatment, 1) $P<0.05$; the same time between-group comparison, 2) $P<0.05$

 

3.2.3 Between-group comparison in QOL score

After treatment, the QOL scores in both groups were markedly increased ($P<0.05$); and there was significant between-group statistical difference ($P<0.05$). The follow-up visit showed significant between-group differences in physical health, psychological, social relationships, overall perception of QOL and overall perception of health ($P<0.05$). These findings indicated that mild-warm moxibustion could obtain a better effect on QOL than CPM (Table 4).

**Table 4. Comparison in QOL score ($\bar{x}\pm s$, point)**

| Group | *n* | Time | Physical health | Psychological | Social relationships | Environment | Overall perception of QOL | Overall perception of health |
|---|---|---|---|---|---|---|---|---|
| Moxibustion | 58 | Before treatment | 61.2±7.3 | 57.1±6.9 | 55.3±7.0 | 45.8±5.9 | 3.1±0.4 | 3.1±0.5 |
| | | After treatment | 9.1±9.6[1)2)] | 90.0±9.1[1)2)] | 83.2±9.2[1)2)] | 59.4±6.5[1)2)] | 4.2±0.5[1)2)] | 4.3±0.6[1)2)] |
| | | Follow-up visit | 90.5±11.2[2)] | 87.6±9.3[2)] | 80.2±8.7[2)] | 55.8±7.2 | 4.0±0.4[2)] | 4.1±0.5[2)] |
| CPM | 57 | Before treatment | 60.8±7.2 | 58.8±7.0 | 54.6±6.3 | 46.6±6.2 | 3.1±0.3 | 3.1±0.5 |
| | | After treatment | 71.9±8.1[1)] | 68.1±7.8[1)] | 65.7±8.8[1)] | 53.8±6.8[1)] | 3.5±0.5[1)] | 3.6±0.5[1)] |
| | | Follow-up visit | 70.1±8.0 | 67.3±8.9 | 65.2±7.9 | 50.3±8.3 | 3.4±0.5 | 3.4±0.5 |

Note: The intra-group comparison before and after treatment, 1) $P<0.05$; the same time between-group comparison, 2) $P<0.05$

## 4 Discussion

Sub-health is defined as an intermediate or the third state between health and disease, which is characterized by some disturbances in psychological behaviors or physical characteristics, or in some indices of medical examination, with no typical pathologic features. Sub-health population may manifest a low stamina and poor adaptability. Over the recent years, sub-health status has attracted research attention from medical communities. Chinese medicine is distinctively effective for sub-health status[7]. However, there is no standardized research design and methodology yet. It is, therefore, of great urgency to apply scientific design to interventional studies on sub-health status.

National survey has shown that fatigue-related sub-health affects more than 25% of the respondents[8]. In Chinese medicine, fatigue is a deficiency syndrome due to consumption of qi and blood. Prolonged fatigue is often a warning sign of clinical conditions. Since excessive fatigue may trigger body-mind conditions, it's essential to apply timely intervention to fatigue[9-11]. Liu YY found that herbal cake-partitioned moxibustion combined with health advice can benefit qi and blood, boost the immune system and improve sub-health status[12]. Wang JD, *et al*, found that unblocking Governor Vessel and warming yang moxibustion benefit people with a yang-deficiency constitution and improve their clinical symptoms, QOL and fatigue[13]. Cheng M, *et al*, reported that moxibustion on Shenque (CV 8), Guanyuan (CV 4), Zusanli (ST 36), Pishu (ST 20), and Shenshu (BL 23) can regulate blood cells in young and middle-aged sub-health population[14].

In this study, a total of 115 subjects finished the trial of mild-warm moxibustion on Qihai (CV 6), Guanyuan (CV 4), Zhongwan (CV 12), Tianshu (ST 25), Zusanli (ST 36) and Sanyinjiao (SP 6). After treatment, there were significant intra-group differences in fatigue score, immune items and QOL score ($P<0.05$); and there were significant between-group differences in fatigue score, levels of IgM and IgG, NK cell activity and QOL score ($P<0.05$). The follow-up visit showed significant between-group differences in fatigue score, physical health, psychological, social relationships, overall perception of QOL and overall perception of health ($P<0.05$). These findings indicate that mild-warm moxibustion can improve fatigue symptoms, immune function and QOL and has a good long-term effect.

The advance in modern preventive medicine allows for a new opportunity for further development of 'intervention before disease onset' in Chinese medicine. Despite its unique efficacy in addressing sub-health, in-depth studies on moxibustion are still needed[15], involving the intervention time, selection of points and course of treatment.

**Conflict of Interest**

There was no potential conflict of interest in this article.

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**Statement of Informed Consent**

Informed consent was obtained from all individual participants included in this study.

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