

## **Herb foot-bath has improving effects on sleep quality and symptom distress of maintenance hemodialysis patients.**

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### **Abstract**

Hemodialysis (HD) is an incomplete renal substitutive therapy to interchange blood and dialyzate between semipermeable membrane so as to clean metabolic wastes and toxic products, maintain electrolyte and acid-base balance, and eliminate excessive moisture from body. Because of double affliction of the pain itself and treatment induced complication, most of Maintenance Hemodialysis (MHD) patients are bothered by influenced sleep quality and other symptom distress. In the study, we set out to investigate the intervention effect of herb foot-bath therapy to improve sleep quality and symptom distress for them. It was an experimental study in two stages including preliminary screening survey and herb foot-bath intervention. 142 MHD patients from Xiangya Hospital of Central South University and the Third Hospital of Central South University in accordance with inclusive criteria were randomly divided into control and intervention group. Patients in intervention group were intervened by regular herb foot-bath for 4 w. Pittsburgh Sleep Quality Index (PSQI) and Dialysis Symptom Index (DSI) were applied to quantify sleep quality and symptom distress of MHD patients. The data were analysis by SPSS19.0. The results showed that a majority of MHD patients were undergoing somnopathy and most of them experienced several symptoms at the same time with high scores of PSQI and DSI. Sleep quality was positively correlated with the symptom burden. To some extent, it was found that herb foot-bath therapy can effectively improve sleep quality of MHD patients and mitigate their symptom distress.

**Keywords:** Maintenance hemodialysis patients, Herb foot-bath, Sleep quality, Symptom distress, PSQI, DSI.

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### **Introduction**

End Stage Renal Disease (ESRD), caused by irreversible loss of renal function to filter body metabolic wastes, salts and water, is the terminal stage of all progressive renal diseases [1]. The morbidity of ESRD is yearly increasing by 8% average with nearly 50-200 patients in one million natural populations worldwide [2]. At present, the most effective therapy of ESRD is still renal replacements, i.e. Hemodialysis (HD), Peritoneal Dialysis (PD) and kidney transplant. However, because of limiting factors of kidney transplant, such as expensive cost, limiting renal sources and high risk, a majority of ESRD patients still require Maintenance Hemodialysis (MHD) as substitutive therapy throughout their lives. Nowadays, with continuous improvement of HD technique and equipment, long-term survival rate of MHD patients is rising gradually, and the treatment goal of MHD is changed from prolonging survival time to improving life quality and social rehabilitation of patients [3,4].

Due to the pain of disease itself and complication induced by HD treatment, MHD patients are commonly bothered by influenced sleep quality and other symptom distress, which is closely related to their morbidity and death rate [5-7]. According to recent research, nearly 60-80% of MHD patients suffered from somnopathy which appears as poor quality of sleep, insomnia, fatigue and somnolence in the daytime, hypnotic dependence, restless legs syndrome, obstructive sleep apnea, etc. [8,9]. Moreover, through investigating physical health status of ESRD patients, most of patients were bothered by fatigue, pruritus, joint pain, crural paralysis, etc. [10-12]. Symptom of distress is changed with disease process and treatment, severity of which is influenced by numerous factors [13,14].

Several intervention therapies of somnopathy, at present, have been gained some therapeutic effects. Because of expensive cost and easy dependency of medicine therapy as well as difficult grasp and performance of rational-emotive therapy, muscle relaxation training and digital pressure therapy, herb foot-bath therapy is comparatively much easier to be accepted

by patients [15-18]. To our knowledge, there is no such research on improving effect of herb foot-bath therapy on symptom distress and somnolence of MHD patients. Thereby, we set out to investigate the influence factors of symptom distress of MHD patients, and explore the intervention effect of herb foot-bath therapy to improve sleep quality and symptom distress for them. It was an experimental study in two stages including preliminary screening survey and herb foot-bath intervention. The theoretical basis of the study is Health Belief Model (HBM) which is extensively applied to forecast of short- and long-term health risk behavior and behavior change.

## Materials and Methods

### Object of study

MHD patients between 18 and 75 y old in Xiangya Hospital of Central South University and the Third Hospital of Central South University in accordance with inclusive criteria were investigated in the present study. The inclusive criteria are as follow: firstly, the period of MHD is over three months and no surgical operation and change in hemodialysis method are performed within three months; secondly, patient is in stable condition during the experiment; thirdly, patient is voluntary to participate the study with consent, understanding and cooperation. According to scoring method of Pittsburgh Sleep Quality Index (PSQI), MHD patient with over 7 total points was regarded as positive standard of screening. These selected patients were randomly divided into intervention group and control group.

### Pittsburgh sleep quality index (PSQI)

PSQI was designed by Buysse et al. to evaluate sleep quality over one-month time interval [19]. The measure is made up by 19 individual items and invited by 7 components including subjective somnus quality, sleep latency, sleep time, sleep efficiency, somniphathy, hypnotic and daytime dysfunction. Every component is scored with 0-3. The total point of PSQI is cumulative score of each component in the range of 0 to 21. Higher total point signifies worse sleep quality of the testee. According to Chinese norm standard, total point of 7 is the boundary, above 7 refers to low amount of sleeping, the sensitivity is 98.3%, the specificity is 90.2% (Kappa=0.89, P<0.01).

### Dialysis symptom index (DSI)

The scale of DSI, containing 5 mental and 25 physical symptoms, was designed by Steven [20]. The frequency and severity of symptom occurrence are involved in the investigation to assess emergent symptom and its frequency, severity and distress degree. The occurrence of symptom is analysed in the form of no or yes (no=0, yes=1). Its frequency and severity are measured through four-point Likert scale method: occasionally/slight=1; often/moderate=2; frequently/severe=3; always/very serious=4. The degree of distress is tested *via* five-point Likert scale method: no distress=1; slight distress=2; moderate distress=3; severe distress=4; very severe

distress. The higher scores indicate the more severe degree of distress. The scale is with 0.923 of Cronbach's  $\alpha$  and 0.939 of content validity.

### Herb prescription

All the herbs were obtained from Longjiang Medicinal Materials Co. Ltd. (Heilongjiang, China). The herb prescription for intervention group was composed of 30 g *Agastache rugosus*, 15 g *Herba eupatorii*, 10 g *Safflower carthamus*, 30 g *Radix rehmanniae* recen, 20 g *Angelica sinensis* and 30 g *Radix paeoniae alba*. Herbs were packed by a gauze bag and handed out to patients in intervention group.

### Herb foot-bath treatment

Herbs packed by gauze bag were put into a footbath with boiled water. Firstly, feet were put above the footbath in water vapor. Until the water temperature was cooled to 38-43°C, feet were put in water for foot bath. During the time of foot bath, the height of water should be over ankles but below knees. If it cooled down, hot water could be added to keep the temperature of water suitable. A course of treatment was four weeks; the intervention time was before nightly bedtime every day. The duration of each intervention time was 30-40 min, if patient was older than 70, 30 min or below of foot bath was better. Once symptoms such as uncomfortableness, profuse sweating, tachycardia and dizziness occurred, patient should stop the intervention and rest in bed. After foot bath, foot should be dried and kept warm. All situations of intervention including any uncomfortable symptom have to be recorded every day.

### Data collection

Questionnaires were distributed and withdrew on the spot. In principle, the questionnaire was filled out by the patient autonomously. Requirements and appeared doubts about the questionnaire were explained by the unified instruction to maintain completeness and correctness.

### Statistical analysis

Database was set up by the means of SPSS19.0. Data was double checked and input by two persons. Statistical significance was defined as P<0.05.

## Results

### Over four fifths of MHD patients were bothered by somniphathy

The base line results of PSQI showed that 27 cases of patients (18.89%) slept well, and 116 cases (81.11%) suffered from somniphathy. The mean score of PSQI was  $10.96 \pm 4.46$ . The average scores were respectively  $1.62 \pm 0.838$  of subjective sleep quality,  $2.03 \pm 1.077$  of the time of falling sleep,  $1.81 \pm 1.081$  of sleeping time,  $1.61 \pm 1.139$  of sleeping effect,  $1.54 \pm 0.591$  of the handicap of sleeping,  $0.43 \pm 1.003$  of the drugs of

hypnosis and  $1.92 \pm 0.953$  of function handicap in daytime (Table 1).

**MHD patients suffered from different degree of symptom distress**

The prevalence of every distress symptom was 13.3-72 %. The mean total score of distress symptom was  $76.69 \pm 37.95$ , lack of strength, dry mouth, festless sleep, difficulty in falling sleeping, sexual hypoactivity, difficulty in sexual excitement, pruritus, dysphoria, worry and edema of lower extremity were ten most frequently occurred symptoms with over 50% of incidence rate. The most severe symptoms were difficulty in falling sleep, restless leg, festless sleep, lack of strength and anhelation (Table 2). The most frequently occurred symptoms were difficulty in falling sleep, festless sleep, lack of strength, anorexia and dry mouth. Multivariable stepwise regression indicated that symptom distress was statistically correlated to the total score of PSQI, the education level and the course time of chronic renal disease of MHD patients in the study ( $P < 0.05$ ). By the means of Spearman correlate test, it was showed that the total score and each dimensionality of PSQI were positively correlated with those of DSI, which implied the positive correlation of sleep quality and symptom distress (Table 3).

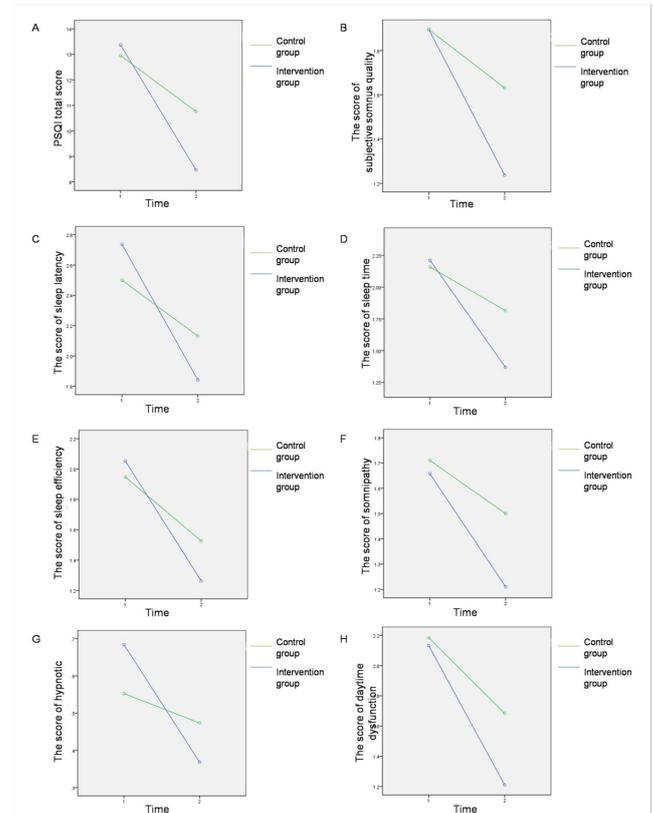
**Herb foot bath decreased total score of PSQI in intervention group**

Through comparing the PSQI scores in control and intervention group, it was detected by two independent-samples t-test and Mann-Whitey U test that there were significant differences in PSQI total score, subjective somnus quality, sleep time, somniphathy and daytime dysfunction between two groups ( $P < 0.05$ ) (Table 4). Paired-samples t-test and nonparametric Wilcoxon test showed that the score of PSQI in intervention group was declined markedly after intervention ( $P < 0.05$ ). In the control group, however, there was no statistics significance in the dimensions of subjective somnus quality, sleep latency, sleep time, sleep efficiency, somniphathy and hypnotic ( $P > 0.05$ ) (Table 5). Through repeated measures analysis variance, it was found that the main effects time on PSQI and the interactions between time and intervention on above variations were both statistically significant (Figure 1).

**Herb foot bath decreased total score of DSI in intervention group**

By the means of independent-samples t-test and Mann-Whitney U test to compare the DSI scores in control and intervention group, there were significant differences found in the total scores of DSI, the degree of symptom distress, the severity of symptom and the occurrence number of symptom between two groups ( $P < 0.05$ ) (Table 6). The results of paired-samples t-test and nonparametric Wilcoxon test showed that after intervention, the DSI scores in intervention group was reduced obviously but not significantly changed in control group. The differences in the DSI score, the degree of

symptom distress, the frequency of occurred symptom, the severity of symptom and the number of symptom between the pre- and post-intervention were significant ( $P < 0.05$ ) (Table 7). Repeated measures analysis of variance showed that the main effects of time on DSI were statistically significant ( $P < 0.05$ ). There were significant interactions between time and intervention on the total score of DSI and other dimensions ( $P < 0.05$ ) (Figure 2).



**Figure 1.** Interaction analysis of PSQI scores and the main effects of time between control and intervention group through repeated measures analysis variance. A: The primary time effect and interaction between time and intervention on the total score of PSQI had statistically significance; B: The primary time effect and interaction between time and intervention on the score of subjective somnus quality had statistically significance; C: The primary time effect and interaction between time and intervention on the score of sleep latency had statistically significance; D: The primary time effect and interaction between time and intervention on the score of sleep time had statistically significance; E: The primary time effect and interaction between time and intervention on the score of sleep efficiency had statistically significance; F: The primary time effect and interaction between time and intervention on the score of somniphathy had statistically significance; G: The primary time effect and interaction between time and intervention on the score of hypnotic had statistically significance; H: The primary time effect and interaction between time and intervention on the score of daytime dysfunction had statistically significance.

**Table 1.** The PSQI score of MHD patients.

Factor	Score ( )
Subjective somnus quality	$1.62 \pm 0.838$

Sleep latency	2.03 ± 1.077
Sleep time	1.81 ± 1.081
Sleep efficiency	1.61 ± 1.139
Somnipathy	1.54 ± 0.591
Hypnotic	0.43 ± 1.003
Daytime dysfunction	1.92 ± 0.953
PSQI total score	10.96 ± 4.455
Data were presented as mean ± SD, n=142.	

**Table 2.** The DSI score of MHD patients.

Item	Score range	Score ()
DSI total score	60-360	76.69 ± 37.95
Degree	0-120	23.36 ± 11.02
Frequency	30-120	29.83 ± 14.64
Severity	30-120	24.51 ± 12.74
Occurrence number	0-30	13.12 ± 5.27
Data were presented as mean ± SD, n=142.		

**Table 3.** Correlation analysis of sleep quality and symptom distress of MHD patients.

Item	DSI total score	Degree	Frequency	Severity
PSQI total score	0.527**	0.516**	0.522**	0.525**
Subjective somnus quality	0.439**	0.445**	0.426**	0.437**

**Table 5.** Comparison of PSQI scores between pre- and post-intervention by the means paired-samples t-test and nonparametric Wilcoxon test.

Item	Intervention group		z	P	Control group		z	P
	Before	After			Before	After		
PSQI total score	13.37 ± 3.26	8.47 ± 2.82	-5.39	0.000**	12.95 ± 3.14	10.76 ± 3.04	-5.236	0.000**
Subjective somnus quality	1.89 ± 0.73	1.24 ± 0.59	-4.33	0.000**	1.89 ± 0.79	1.63 ± 0.71	-1.456	0.145
Sleep latency	2.74 ± 0.55	1.84 ± 0.82	-5.26	0.000**	2.16 ± 0.82	2.13 ± 0.91	-1.742	0.081
Sleep time	2.21 ± 0.94	1.37 ± 0.85	-4.768	0.000**	1.95 ± 1.06	1.82 ± 0.97	-1.512	0.13
Sleep efficiency	2.03 ± 1.05	1.26 ± 0.98	-4.817	0.000**	1.95 ± 1.06	1.53 ± 0.91	-1.929	0.054
Somnipathy	1.66 ± 0.53	1.21 ± 0.17	-3.9	0.000**	1.71 ± 0.61	1.50 ± 0.37	-1.598	0.11
Hypnotic	0.69 ± 1.21	0.37 ± 0.75	-3.051	0.002**	0.55 ± 1.11	0.47 ± 0.96	-1.732	0.083
Daytime dysfunction	2.13 ± 0.84	1.21 ± 0.70	-4.917	0.000**	2.18 ± 0.87	1.68 ± 0.71	-2.512	0.012*
Data were presented as mean ± SD, n=71, *P<0.05 and **P<0.01 vs. control group.								

**Table 6.** Comparison of DSI scores between control and intervention group through t-test and Mann-Whitney U test.

Item	Intervention group	Control group	t/z	P
DSI total score	58.45 ± 20.12	75.08 ± 34.09	-2.026 <sup>^</sup>	0.043*

Sleep latency	0.246**	0.262**	0.232**	0.242**
Sleep time	0.410**	0.399**	0.406**	0.421**
Sleep efficiency	0.469**	0.449**	0.475**	0.465**
Somnipathy	0.356**	0.351**	0.354**	0.356**
Hypnotic	0.230**	0.218**	0.239**	0.212*
Daytime dysfunction	0.417**	0.392**	0.418**	0.415**
Data were presented as mean ± SD, n=142, *P<0.05 and **P<0.01 vs. control group.				

**Table 4.** Comparison of PSQI scores between control and intervention group through t-test and Mann-Whitney U test.

Item	Intervention group	Control group	Z	P
PSQI total score	8.47 ± 2.82	10.76 ± 3.04	-2.98	0.003**
Subjective somnus quality	1.24 ± 0.59	1.63 ± 0.71	-2.237	0.025*
Sleep latency	1.84 ± 0.82	2.13 ± 0.91	-1.498	0.141
Sleep time	1.37 ± 0.85	1.82 ± 0.97	-2.073	0.038*
Sleep efficiency	1.26 ± 0.98	1.53 ± 0.91	-1.23	0.231
Somnipathy	1.21 ± 0.17	1.50 ± 0.37	-2.444	0.015*
Hypnotic	0.37 ± 0.75	0.47 ± 0.96	-0.19	0.831
Daytime dysfunction	1.21 ± 0.70	1.68 ± 0.71	-2.333	0.019*
Data were presented as mean ± SD, n=142, *P<0.05 and **P<0.01 vs. control group.				

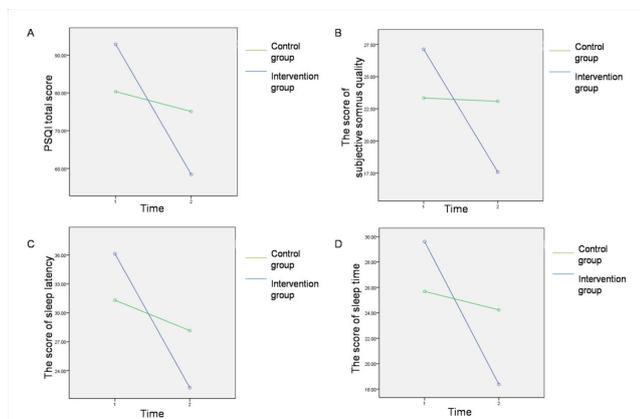
Degree	17.57 ± 5.82	23.08 ± 9.86	-2.367 <sup>^</sup>	0.018*
Frequency	22.24 ± 8.23	28.16 ± 13.44	-1.862 <sup>^</sup>	0.063
Severity	18.37 ± 6.75	24.24 ± 11.22	-2.253 <sup>^</sup>	0.024*

Occurrence number	10.37 ± 3.66	12.76 ± 4.59	-2.51	0.014*
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**Table 7.** Comparison of DSI scores between pre- and post-intervention by the means paired-samples t-test and nonparametric Wilcoxon test.

Item	Intervention group		t	P	Control group		z/t	P
	Before	After			Before	After		
DSI total score	92.87 ± 35.69	58.45 ± 20.12	13.849	0.000**	80.34 ± 37.96	75.08 ± 34.09	-2.381 <sup>A</sup>	0.017*
Degree	27.13 ± 10.14	17.57 ± 5.82	12.34	0.000**	23.34 ± 10.79	23.08 ± 9.86	-0.029 <sup>A</sup>	0.977
Frequency	36.13 ± 13.74	22.24 ± 8.23	17.404	0.000**	31.32 ± 15.0	28.16 ± 13.44	-3.418 <sup>A</sup>	0.001**
Severity	29.61 ± 12.36	18.37 ± 6.75	11.142	0.000**	25.68 ± 12.65	24.24 ± 11.22	-1.647 <sup>A</sup>	0.099
Occurrence number	14.66 ± 4.62	10.37 ± 3.66	14.746	0.000**	13.89 ± 5.43	12.76 ± 4.59	2.726	0.010**

Data were presented as mean ± SD, n=71, <sup>A</sup>refers to z, \*P<0.05 and \*\*P<0.01 vs. control group.



**Figure 2.** Interaction analysis of DSI scores and the main effects of time between control and intervention group through repeated measures analysis variance. A: The primary time effect and interaction between time and intervention on the total score of DSI had statistically significance; B: The primary time effect and interaction between time and intervention on the score of symptom distress degree had statistically significance; C: The primary time effect and interaction between time and intervention on the score of symptom distress frequency had statistically significance; D: The primary time effect and interaction between time and intervention on the score of symptom distress severity had statistically significance.

**Discussion**

The study investigated sleep quality and symptom distress of 142 MHD patients, and probed into the effects of herb foot-bath on them. PSQI and DSI were utilized to quantify sleep quality and symptom distress of MHD patients. According to our results, sleep quality was positively correlated with the symptom burden. To some extent, it was found that herb foot-bath therapy can effectively improve sleep quality of MHD patients and mitigate their symptom distress.

We found about 81.11 % of them suffered from somniphathy, and the ratio of disturbed patients in the present study was in accord with the results in previously published researches [21,22]. The total score of PSQI was detected to be 10.96 ± 4.46. In the study, the prevalence of somniphathy was high,

which probably resulted from long course of disease induced complicated state and complication of patients. MHD patients of the study generally had more than five year of course of disease, and most of them were gerontal patients who may have been troubling but neglected sleep problems and had never took improvement measures, resulting in increasingly severe sleep disorder. Most of MHD patients mainly complained of difficulty in falling sleep, poor quality of sleep, festless sleep, short sleep time and low sleep efficiency. Because of disrupted circadian rhythm induced by insomnia, the physical and psychological health of these patients were badly influenced by somnolence and lack of strength in the daytime, which further affecting their living quality.

The number of symptom distress in the study was found to be 3-25, averagely 13.12 ± 5.27 per patient, and the total DSI score of symptom distress was in the range of 12 to 193, averagely 76.69 ± 37.95. The results demonstrated that the majority of MHD patients were undergoing various painful symptoms distress simultaneously. As MHD patients suffered from double affliction of somatization from disease itself and relative symptoms induced by dialysis treatment which reduced quality of life, symptom distress was further aggravated. Moreover, we found symptoms with highest degree were difficulty in falling sleep, restless leg, festless sleep, anhelation and lack of strength; the most frequently occurred symptoms were difficulty in falling sleep, festless sleep, lack of strength, anorexia and dry mouth; the most severe symptoms were respectively difficulty in falling sleep, restless leg, festless sleep, lack of strength and anhelation. To our knowledge, it has been documented that sexual dysfunction was one of symptoms troubled MHD patients badly, but it was not reflected in the study [11,23]. The difference probably resulted from traditional concept of Chinese patients and shame in answering sexual dysfunction related questions.

Through correlation analysis of symptom distress and each dimension of PSQI scale, it was detected that the degree, prevalence and severity of symptom distress were all positively correlated PSQI total score, subjective somnolence quality, sleep latency, sleep time, sleep efficiency, somniphathy, hypnotic and

daytime dysfunction, which indicated that sleep improvement was able to mitigate symptom distress of MHD patients.

Based on Chinese medicine, Chronic Renal Failure (CRF), which is induced by inherent shortage, improper diet, emotional disturbance and recurrent renal diseases, is involved in categories of obstruction and rejection, retention of urine and consumptive disease. Damaged spleen and kidneys, damp turbidity, stasis toxin and internal stagnation are considered as the main mechanisms of CRF. As there exists numerous reflecting regions and acupuncture points on sole of foot, foot is closely related to kidney. The prescription for intervention group was made up by *Agastache rugosus*, *Herba eupatorii*, *Safflower carthamus*, *Radix rehmanniae* recen, *Angelica sinensis* and *Radix paeoniae alba*. *Agastache rugosus* is an aromatic Chinese medicine which has function of inducing perspiration and resolving dampness [24]. *Herba eupatorii* can dissolve turbidities and repel foulness [25]. *Safflower carthamus* is able to invigorate the circulation of blood, stimulate menstrual flow, and improve microcirculation of heart and brain [26]. *Radix rehmanniae* recen possesses sedative effect, mitigates symptoms of patient with hypertension, and obviously improve hypertension induced insomnia [27]. *Angelica sinensis* has a lot of functions including immuno-enhancement, protection of the liver and kidney function, improvement of renal blood flow, oxidation resistance, ameliorating renal fibrosis, promotion of hematopoiesis, etc. *Radix paeoniae alba* has effective of nourishing blood and liver and retaining yin with astringent [28,29].

After intervention of herb foot-bath, the score of PSQI, subjective somnus quality, sleep latency, sleep time, somniphathy and daytime dysfunction of patients in intervention group were significantly decreased in comparison with control group. In addition, by self-comparison, total PSQI score and score in each dimension were also obviously reduced after herb foot-bath compared to pre-intervention. In the study, we found that sleep quality of MHD patients was obviously improved after intervention of herb foot-bath compared with control group, which implied that herb foot-bath could effectively mitigate somniphathy and improve sleep quality of MHD patients. After intervention of herb foot-bath, compared with control group, the total DSI score and scores of the degree, severity and occurrence number of symptom distress were decreased markedly with significant differences. By comparing pre- and post-intervention, the total score of DSI and the scores in dimension of the degree, prevalence, severity and numbers of symptom distress were substantially reduced in intervention group, which indicated the improving effect of herb foot-bath on symptom distress. Herb foot-bath intervention mitigated the degree and severity of symptom distress, and reduced its prevalence and occurrence number. Given the limitation of the study, there may exist placebo effects on the results between control and intervention groups, which is required to be further studied in the future.

## Conclusion

Most of MHD patients suffered from somniphathy and most of them experienced several symptoms at the same time with high scores of PSQI and DSI. The sleep quality was positive correlated with the symptom burden. To some extent, herb foot-bath therapy can effectively improve sleep quality of MHD patients and mitigate their symptom distress.

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