A sham-controlled trial of acupressure on the quality of sleep and life in haemodialysis patients

Zahra Arab,[1] Ali Reza Shariati,[2] Hamid Asayesh,[3] Mohammad Ali Vakili,[4] Hamidreza Bahrami-Taghanaki,[5,6] Hoda Azizi[7]

For numbered affiliations see end of article.

Correspondence to
Dr Hamidreza Bahrami-Taghanaki, Department of Chinese and Complementary Medicine-Mashhad University of Medical Sciences, East Razi Street, Mashhad 9135913556, Iran; bahramihr@mums.ac.ir

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ABSTRACT

Background Sleep disorder in haemodialysis patients can lead to disturbance in their psychosocial function and interpersonal relations, and reduced quality of life. The aim of the present study was to investigate the effect of acupressure on the quality of sleep of haemodialysis patients.

Methods In a randomised controlled trial, 108 haemodialysis patients were randomly divided into three groups: true acupressure, placebo acupressure, and no treatment. The two acupressure groups received treatment three times a week for 4 weeks during dialysis. Routine care only was provided for the no treatment group. The main study outcome was sleep quality.

Results The total Pittsburgh Sleep Quality Index score decreased significantly from 11.9±3.13 to 6.2±1.93 in the true acupressure group, from 11.3±3.69 to 10.6±3.82 in the sham acupressure group, and from 10.9±4.10 to 10.7±3.94 in the no treatment group. There was a significant difference between groups ($p<0.001$).

Conclusions Acupressure seems to have a positive effect on the sleep quality in haemodialysis patients.

Clinical trial registration IRCT201106145864N2.

INTRODUCTION

Major sleep problems are observed in more than 85% of patients with end stage renal disease receiving haemodialysis.[1] If sleeplessness continues for a long period, it leads to reduced quality of life. Studies have shown that the life quality of haemodialysis patients is lower than that of healthy individuals, transplant patients, and peritoneal dialysis patients.[2] The diagnosis and treatment of sleep disorders in such cases led to improved quality of life.[3–5]

Acupressure is a treatment method that may improve sleep by releasing neural mediators that regulate physical processes, inducing the body to become relaxed and improving the quality of sleep.[6]

Tsay *et al*[7] found that massage of pressure points was effective in improving the sleep quality and life quality of end-stage renal patients. Maa *et al*[8] also showed a significant improvement in the life quality of patients with asthma with acupressure. Three other research teams reported the positive role of acupressure in the *Shenmen* point of the wrists on the sleep quality of patients.[6 9 10] Considering the small number of reports on the topic, we aimed to investigate the effect of acupressure on the sleep and life quality in patients undergoing haemodialysis by means of a controlled trial.

METHODS

We conducted a randomised controlled trial on 108 haemodialysis patients in Imam Reza, Hasheminejad and Imam Zaman Educational Hospitals in Mashhad, Iran in 2011. The study was approved and supported by Golestan University of Medical Sciences (research code 2484.35). The trial was also registered in the Iranian Registry for Clinical trials (IRCT201106145864N2). The inclusion criteria were as follows: age 18–70 years; a 6-month history of dialysis three times each week, 4 h each time; a Pittsburgh sleep scale score ≥5; having complete consciousness, hearing and speaking ability; no diagnosed psychological disorder requiring daily medication; no history of cancer, lupus, skin disease, advanced cardiac failure, insulin dependent diabetes or stroke; no limb amputation or scar in the pressure points; and at least basic formal education.

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We based our sample size calculation on the results of a similar study in which the mean changes in sleep quality index scores were 5.0 for true points and 2.0 for false points,[11] and the highest estimated SD was 4.25. Using a confidence level of 95% and power of 80%, and allowing for loss to follow-up, we estimated that 36 participants for each group (in total 108) were required for this study.

After enrolment, patients were randomly allocated in three groups of 36: acupressure, placebo acupressure, and no treatment. The study was single-blind. The randomisation process was concealed by using sealed envelopes, and the person responsible for enrolment did not know which group the patients would be allocated to. The assessor and statistician were blind to the study groups, as were patients in real and sham acupressure groups. After allocating the intervention group for each patient and taking a signed informed consent, the baseline data were collected using the Pittsburgh sleep quality index (PSQI) questionnaire, the sleep chart, and SF-36. The study lasted for 4 weeks after which time the study outcomes were assessed again.

The intervention group received acupressure in the bilateral *Shenmen* points (HT7), three times a week for 4 weeks. HT7 is located on the wrist, on the radial side of flexor carpi ulnaris, in the depression at the proximal border of the pisiform bone. A pressure equal to 3–4 kg was applied for 8 min with the thumb (3 min on each point with 2 min rest between) using a circular movement at the rate of two rotations per second, 1 h after dialysis.

The control groups received either sham acupressure or no treatment. The sham acupressure was performed on points at 0.5 cm from the true points and not on the traditional meridian pathways. The third group received no treatment other than routine daily care. Acupressure was performed by a researcher who had been trained by a faculty member acupuncturist for more than a month. The same practitioner provided both active and control acupressure interventions. Before the study, the precision of locating the intended points and using the correct technique was confirmed with 100% accuracy on 20 haemodialysis patients. To establish consistency of performance, the amount of pressure applied by the researcher's left and right thumb on each point was measured using a scale with ±20 g accuracy up to 6 kg; 30 measurements were recorded over a period of 10 days at a fixed location. The results showed that the mean pressure of the right and left hand thumb were 3.41 kg and 3.50 kg (SD=0.221), respectively.

Outcome measurement

The primary outcome was sleep quality which was measured by the PSQI questionnaire and a sleep chart. The PSQI was completed for each patient before and after the study. The questionnaire assesses the patient's sleep quality during the previous 4 weeks, and consists of nine questions (one with 10 component questions), each scored on a 0–3 scale. Responses are combined in a standardised way to generate seven component scores and one global score. The total score ranges from 0 to 21. A score above 5 is considered as poor sleep quality.[12] The validity of this questionnaire for the Iranian population has been confirmed based on the study by Farhadi Nasab and Azimi.[13] Farrahi *et al* achieved a sensitivity of 100%, a specificity of 93%, and a Cronbach $\alpha=0.89$ for the Persian version of this questionnaire.[14] In the current study, a reliability of $\alpha=0.71$ was obtained for the internal components of the sleep quality questionnaire.

The sleep chart was also used to record the previous night's subjective sleep quality on a scale of 0–10, and the number of awakenings. The sleep chart was derived from the study by Rogers *et al* which showed 87% consistency with the polysomnography results.[11 15–17] The quality of sleep was measured by the sleep chart before the study, nine times through the study period, and after the study. In each measurement, the mean sleep quality of three consecutive days was calculated.

The secondary outcome was the health-related quality of life, measured with a questionnaire (SF36) which uses eight dimensions, each scored from 0 to 10. Higher scores indicate higher quality of life.[18 19] This questionnaire has been standardised in Iran by Montazeri *et al*.[20] In this study the internal reliability was calculated as 84% using Cronbach's α.

Statistical analysis

In data analysis the SPSS package V.6 was used. Only patients providing follow-up data were included in the analysis. The data were normally distributed and the variances were equal. Analysis of variance (ANOVA) was used to compare groups for the total PSQI score, followed by the Bonferroni test to compare groups two by two.

The baseline characteristics of patients were compared among the three groups before the study using the χ^2 test. For the sleep chart data, ANOVA was used for baseline comparisons, and the Kruskal-Wallis was applied during and after the study to compare the three groups; the Mann-Whitney test was used to compare groups two by two. For the number of nighttime awakenings, the Kruskal-Wallis test was used to compare between group differences. For the quality of life, the one-way variance analysis test and the Kruskal-Wallis test were applied.

RESULTS

One hundred and eight patients with end stage renal disease who were receiving haemodialysis were enrolled and randomised. During the study period 15 participants (four, six, and five from the acupressure, placebo acupressure, and no treatment groups,

Table 1 Baseline characteristics of participants

	Acupressure (n=32)	Placebo acupressure (n=30)	No treatment (n=31)
Male sex, N (%)	17 (53.1%)	17 (56.7%)	16 (51.6%)
Occupation			
Working	6 (18.8%)	9 (30.0%)	11 (35.5%)
Retired	6 (18.8%)	2 (6.7%)	4 (12.9%)
Jobless	20 (6.5%)	19 (63.3%)	16 (51.6%)
Weekly exercise N (%)			
None	19 (59.4%)	15 (50%)	13 (41.9%)
Once	1 (3.1%)	5 (16.7%)	7 (22.6%)
2–3 times	7 (21.9%)	6 (20%)	9 (29%)
>3 times	15 (15.6%)	4 (13.3%)	2 (6.5%)
Smoking N (%)	2 (6.2%)	1 (3.3%)	1 (3.2%)
Chronic pain N (%)	17 (53.1%)	15 (50%)	13 (41.9%)

respectively) were withdrawn for different reasons such as transplantation, absence for travel, hospitalisation, major stress due to a close relative's death, and unwillingness to continue in the study.

The baseline characteristics of patients were no different between the study groups (table 1).

Table 2 shows the total score of the Pittsburgh quality of sleep before and after the study period in each group. The total PSQI score was no different between groups before the study ($p>0.05$, ANOVA). A significant difference in the total PSQI was observed between the three groups after the study ($p<0.001$). When comparing the groups two by two using the Bonferroni correction test, a significant difference in the total score was observed between the true acupressure and placebo acupressure groups ($p<0.001$), and also between the true acupressure and no treatment groups ($p<0.001$). There was no difference between the placebo acupressure and the no treatment groups.

The sleep chart data analysis showed an increase in sleep quality during the study period in all groups, with significant difference between the groups ($p\leq0.001$). Table 3 shows the improvement in sleep quality with time.

The number of nighttime awakenings in all three groups is shown in table 4. There was a significant difference between the three groups in the number of nighttime awakenings before and after the study using the Kruskal–Wallis test ($p<0.001$).

Table 5 shows the quality of life components and domains before and after study in each group.

Table 3 Mean sleep quality according to sleep chart before, during, and after the study

	Acupressure (n=32)	Placebo acupressure (n=30)	No treatment (n=32)
Before the study	4.8±0.78	4.8±0.97	4.3±0.85*
2nd measurement	5.9±0.74	5.3±1.08	4.1±0.73†
3rd measurement	6.3±0.61	5.9±0.76	4.3±0.47†
4th measurement	6.6±0.51	5.5±0.75	5.0±0.64†
5th measurement	6.7±0.52	5.8±0.72	5.6±0.59†
6th measurement	6.6±0.44	5.9±0.48	5.0±0.53†
7th measurement	6.5±0.44	5.7±0.85	4.4±0.49†
8th measurement	7.1±0.50	6.1±0.52	5.1±0.55†
9th measurement	7.3±0.57	6.2±0.70	5.0±0.56†
After the study	7.3±0.60	6.1±0.60	4.6±0.58†

Values are given as mean±SD; each value represents the mean sleep quality of 3 consecutive days.
*There was no significant difference between groups before the study, using one-way analysis of variance (ANOVA).
†Significant difference between three groups using Kruskal–Wallis ($p<0.001$); and significant difference between acupressure and placebo acupressure, and between acupressure and control (Mann–Whitney).

DISCUSSION

This study showed improved sleep quality in renal dialysis patients after receiving acupressure. A significant difference in the total score of the PSQI and all the component subscores except for the use of sleeping medication was shown in the acupressure group in comparison to the placebo acupressure and no treatment groups.

These findings confirm the role of acupressure on the *Shenmen* points of the wrists in improving the sleep quality of dialysis patients as suggested by previous studies.[7 15] Tsay and Rong compared true acupressure, placebo acupressure and no treatment, and observed greater improvement in the PSQI and all the component subscores except for sleep latency, use of sleeping medication, and sleep disturbances in the true acupressure group in comparison to the two control groups. In 62 haemodialysis patients, Nasiri *et al*[15] showed a significant difference in the quality of sleep based on the PSQI between acupuncture and control. Hoseinabadi *et al* investigated the effect of acupressure compared with routine daily care and verbal communication on the sleep quality in 90 elderly patients and found significant differences between real acupuncture and both placebo acupuncture and untreated controls for PSQI. There was also a significant difference between real and placebo

Table 2 Sleep quality according to PSQI before and after the study period

	Acupressure (n=32)		Placebo acupressure (n=30)		No treatment (n=31)	
	Before	After	Before	After	Before	After
Total PSQI score	11.9±3.13	6.2±1.93	11.3±3.69	10.6±3.82	10.9±4.10	10.7±3.94

PSQI, Pittsburgh sleep quality index; values are given as mean±SD.

Table 4 Number of nighttime awakenings before and after the study

Study group	Before	After
Acupressure (n=32)	3.1±0.9	2.2±0.7
Placebo acupressure (n=30)	3.1±0.8	2.7±0.97
No treatment (n=31)	2.9±0.9	2.5±0.7

Significant difference between groups (p<0.001, Kruskal-Wallis).

acupuncture for sleep latency subscale score.[11] Regarding the schedule for providing the intervention, three times a week for 4 weeks, the present study was similar to the studies by Hoseinabadi *et al*,[11] Nasiri *et al*,[15] and Chen *et al*.[21]

Nordio *et al* (2008) reported a significant normalisation in the melatonin metabolite content in the acupressure group in comparison to the controls. Different tissues underlie HT7 and include the flexor digitorum profundus muscle, the flexor digitorum superficialis muscle, the flexor carpi ulnaris muscle, the ulnar artery, and the ulnar nerve. The most likely mechanism seems to be deep stimulation of the muscles around and beneath this point, similar to acupuncture needling. Massage seems to be effective in modulating the nervous system and restoring homeostasis through increased endorphin secretion, reducing pain, and promoting relaxation.

We chose HT7 because it is the most commonly used point in acupressure studies; it is also the common point in most traditional acupuncture protocols for insomnia, and is supported by more clinical evidence than any other point for insomnia. It was used alone in the recent clinical trials.[6 22 23] Other acupressure points with possible effects on sleep disorders include PC6, GB20, EX–HN3 (*Yintang*), CV17, BL10, GV16, KI6, BL62, TE17, and GB34.[24] They could be included in further studies, as it is possible that pressing on different tissues could have different central nervous system effects.

One of the limitations of this study is the risk of unconscious unblinding of patients by the practitioner. Additionally, despite training, we cannot be sure that the pressure applied was consistent in the two groups. Another limitation is that due to the unwillingness of patients and the lack of time, follow-up of the acupressure effect after completion of the intervention was not possible. There were a number of dropouts including some due to a lack of response, which reduces the rigour of the finding. Also, the mean PSQI score at the end was over 5, indicating that sleep was still classified as 'poor'. In addition, despite instructions to the contrary, it is possible that either the patient or a family member might have tried apply acupressure at home, whether in the correct or incorrect manner, which was uncontrollable.

In conclusion, our findings support those of other clinical trials in suggesting that acupressure has some short-term effect in improving the sleep quality of haemodialysis patients. The use of this low-cost and simple method may bring comfort to patients and enhance their quality of life.

Summary points

- Haemodialysis for chronic renal failure is associated with severe insomnia.
- We compared 12 sessions of acupressure with sham (wrong-point) acupressure and with usual care only.
- The improvements in insomnia and several aspects of quality of life in the acupressure group were significantly superior to both control groups, though sleep quality was still classified as poor.

Author affiliations
[1]Samen- al- aeme Hospital, Mashhad, Iran
[2]Department of Internal and Surgical Nursing, School of Nursing and Midwifery, Golestan University of Medical Sciences, Gorgan, Iran

Table 5 Comparison of the quality of life (SF36 scores) before and after study

	Acupressure (n=32)		Placebo acupressure (n=30)		No treatment (n=31)	
	Before	After	Before	After	Before	After
Physical functioning	38.1±9.48	38.5±9.46	37.0±10.47	36.2±9.80	38.1±9.10	38.2±8.90
Role limitation (physical)	29.6±5.40	30.8±5.23**	28.3±6.23	28.7±6.42	29.4±7.43	28.8±7.87
Bodily pain	67.2±8.25	77.0±9.04**	70.4±8.98	70.8±8.26	68.6±8.46	69.4±8.44
General health	41.6±7.58	41.7±7.41	42.0±6.59	42.1±6.63	41.6±5.59	41.2±6.07
Vitality (energy/fatigue)	48.8±7.97	50.6±8.42*	49.0±5.21	49.4±6.19	50.4±5.78	49.4±5.44
Social functioning	54.3±9.30	61.3±9.18**	55.8±11.71	56.7±11.24	65.5±6.35	55.2±6.27
General mental health	58.1±6.06	62.0±5.66**	57.0±6.64	57.3±6.35	58.6±4.51	57.9±4.61*
Role limitation (emotional)	55.0±8.90	60.9±8.79**	54.8±7.80	55.6±8.27	56.6±4.69	56.0±5.79
Physical component score	44.2±5.95	47.0±5.95**	44.4±6.76	44.5±6.52	44.4±6.39	44.4±6.42
Mental component score	54.0±5.91	58.7±5.05**	54.1±5.80	54.7±5.88*	55.5±3.44	54.6±3.58*

Values are mean±SD.
*p≤0.05 within group changes; **p≤0.001 within group changes.

[3]Department of Mental Health, School of Nursing and Midwifery, Qom University of Medical Sciences, Qom, Iran
[4]Department of Biostatistics, School of Medicine, Golestan University of Medical Sciences, Gorgan, Iran
[5]Chinese and Complementary Medicine Research Center, Mashhad University of Medical Sciences, Mashhad, Iran
[6]Department of Complementary Medicine, Mashhad University of Medical Sciences, Mashhad, Iran
[7]Addiction Research Center, Mashhad University of Medical Sciences, Mashhad, Iran

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