



The Effect of Acupuncture on Improvement of Pittsburgh Sleep Quality Index Scores in Geriatric Patients with Insomnia: A Randomized, Sham-Controlled, Single-Blind Clinical Trial

Griselda Tanumas¹, Arya Govinda Rooshoeroe², Agitha Melita Putri^{1*}, Desi Recsanti¹, Felix Halim¹, Firza Syailindra¹, Adiningsih Srilestari³, Hasan Mihardja³



DOI : 10.36216/jpd.v7i2.220

Background: Life expectancy continues to grow gradually in developed countries up to 120. The elderly often complain of insomnia which is influenced by mental health, physical illness, comorbid diseases, and life satisfaction. Moreover, multi-pathological conditions can occur in geriatric patients over the age of 60 with insomnia. In this case, the drugs used can have unwanted side effects.

Objective: This study aimed to compare the effect of acupuncture with *sham* on the difference in Pittsburgh Sleep Quality Index (PSQI) scores after the 8th session in geriatric patients with insomnia.

Methods: This single center, randomized, controlled, single-blind clinical trial on geriatric patients who experienced insomnia at the geriatric and acupuncture polyclinic of RSUPN dr. Cipto Mangunkusumo. Thirty-six (36) eligible subjects with consecutive sampling methods were randomly assigned 1:1 into acupuncture and *sham* groups. PSQI test was conducted at the beginning and end of treatment which will result scores that will be analyzed using the T-Test if they are normally distributed. Otherwise, the Mann-Whitney Test is used.

Result: Thirty-four (34) participants completed the trial and two dropped out. Based on the data analysis result, the average of initial PSQI scores between the acupuncture and *sham* acupuncture groups were not significantly different ($p=0,488$). Meanwhile, the difference in PSQI scores after 8th session in the acupuncture group was greater than *sham* acupuncture ($p=0,013$).

Conclusion: Based on the study results, it was concluded that acupuncture had a greater PSQI score reduction effect than *sham* acupuncture in geriatric patients with insomnia.

Keywords: PSQI Comparison, *Sham* Acupuncture, Sleep Quality, Elderly, T-Test.

¹Medical Acupuncture Specialist Program, Faculty of Medicine, Universitas Indonesia and Cipto Mangunkusumo Hospital, Jakarta, Indonesia;

²Department of Internal Medicine, Faculty of Medicine, Universitas Indonesia and Cipto Mangunkusumo Hospital, Jakarta, Indonesia;

³Department of Medical Acupuncture, Faculty of Medicine, Universitas Indonesia and Cipto Mangunkusumo Hospital, Jakarta, Indonesia.

*Correspondence to:
 Agitha Melita Putri;
 Medical Acupuncture Specialist Program Faculty of Medicine Universitas Indonesia and Cipto Mangunkusumo Hospital, Jakarta, Indonesia;
agithamelitaputri@gmail.com

Received : 14 August 2023

Accepted : 17 September 2023

Published : 31 Oktober 2023

INTRODUCTION

Life expectancy continues to increase linearly until it is estimated to reach the age of 120 years in developed countries. This is accompanied by fertility rates that have decreased for a long time, resulting in a more middle-aged population compared to young people.¹ In Indonesia, the elderly population over the age of 65 years in 2015 reached 16.9 million and is estimated to reach 57.2 million by 2050.² In general, the elderly often complain of insomnia. Several countries recorded a high prevalence of insomnia in the elderly, including South Korea with a prevalence of 29.2% and several countries in Europe with a prevalence of 13-31%.^{3,4} This can be influenced by a decline in mental and physical health, disease-comorbid factors, life satisfaction, and socioeconomic status.^{5,6}

This multifactorial condition can occur in geriatric patients who are over the age of 60 years so it can cause damage to organ systems resulting in geriatric patients suffering from more than one chronic or degenerative disease and experiencing a decrease in functional status.⁷ In this multi-pathological condition, the administration of drugs such as benzodiazepines, diphenhydramine, and antidepressants can have unwanted side effects.^{8,9} In addition, nonpharmacological approaches such as sleep hygiene, cognitive behavioral therapy, stimulus control, and muscle relaxation have not been able to treat insomnia in geriatrics completely.^{8,10}

Based on this, public interest in alternative therapies, such as acupuncture has grown in the last two decades.^{11,12} In this case, the World Health Organization (WHO) also

states that acupuncture therapy is safe if done by trained practitioners because acupuncture only provides minimal side effects compared to drugs and has been shown to have a therapeutic effect on insomnia.¹³ Several studies related to the effects of acupuncture on insomnia have been conducted. Meta-analysis research and systematic review using 2363 subjects with insomnia who were given therapy with a combination of HT7 Shenmen, GV20 Baihui, and SP6 Sanyinjiao proved that acupuncture is superior to *sham* or *placebo* and more effective than pharmacotherapy in improving sleep quality of insomnia patients based on the Pittsburgh Sleep Quality Index (PSQI) assessment.¹⁴ A recent meta-analysis and systematic studies have also proven that acupuncture is effective in improving PSQI scores and the Hamilton Depression Rating Scale (HDRS) on insomnia-related depressive disorders.¹⁵ Thus, this study was conducted to provide evidence of the effectiveness of acupuncture as an alternative nonpharmacological therapy in geriatrics with insomnia if standard therapy does not have a significant effect on improving sleep quality.

MATERIAL AND METHODS

Sample Selection

The population of this study was geriatric patients at the geriatric and acupuncture polyclinic of RSUPN dr. Cipto Mangunkusumo Jakarta who experienced insomnia. In this study, the sample obtained for each treatment group was 18 subjects. Because there were two treatments, the total sample of this study was 36 subjects. This number was determined based on the calculation of sample size formula. We used $Z_{\alpha/2}$ with the $\alpha = 5\%$, of 1.96, Z_{β} with the $\beta = 80\%$, is 0.84, S is the standard deviation based on literature which is 3.04, while $X_1 - X_2$ is a minimum mean difference based on literature which is 3.00. Thus, the minimum sample to be used in this study was 16 subjects. Then, by calculating a drop-out sample proportion estimation, the minimum sample was re-calculated. The drop-out sample estimation was 10%. Therefore, the corrected minimum sample was 18 subjects for each group.

The sampling is carried out by a consecutive sampling method. Every subject who met the inclusion criteria was selected until 36 samples were achieved. All samples obtained were randomly assigned 1:1 into acupuncture and *sham* groups using a computer-generated random sequence, namely *randomizer.org*. The whole sampling process starting from generating the allocation, enrolling, and assigning participants was done by Griselda Tanumas.

To select samples, inclusion, exclusion, and fall criteria are used. The inclusion criteria were geriatric patients, meeting the DSM-5 insomnia diagnosis criteria, and having a PSQI score of greater than five. Exclusion criteria include having a medical emergency, having a coat, wound, infection,

thrombophlebitis, or tumor at the selected acupuncture point, amputation of the upper and lower extremities, blood clotting disorders, speech, and hearing disorders, and using benzodiazepines, nonbenzodiazepines, and antidepressants in the last a week. Meanwhile, the knockout criterion is that the subject does not attend therapy sessions more than once.

Materials

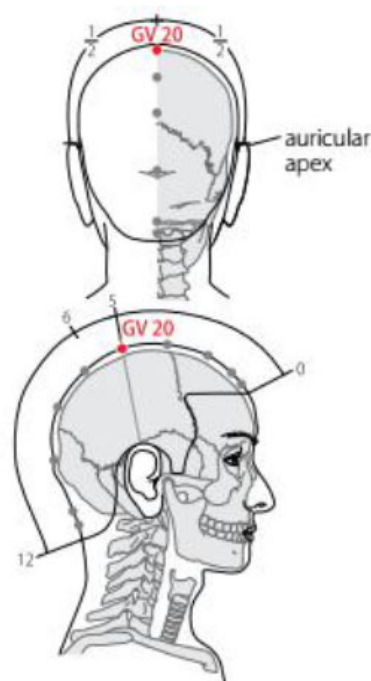
To carry out therapy, tools and materials are needed, including Dong Bang brand disposable acupuncture needles measuring 0.25 x 25 mm, 70% alcohol cotton, plaster, *timer*, gloves, used needle holders, informed consent forms, research forms, stethoscopes, sphygmomanometers, and eye patches. Therapy was given to all study subjects as many as eight sessions with a frequency of twice a week. When performing therapy, the subject is asked to lie down and wear an eye patch. Researchers performed aseptic and antiseptic actions with a 70% alcohol cotton swab on acupuncture points. Next, subjects were given acupuncture therapy and *sham* acupuncture based on a predetermined group division. The acupuncture needles were removed after 30 minutes and thrown into the medical garbage. The last therapeutic step is cleaning the puncture area with a 70% alcohol cotton swab.

Research Procedures

This study was designed to be a single center, randomized, controlled, and single-blind study design. In sequence, the flow of this study began with sampling geriatric patients according to exclusion and inclusion criteria which were then calculated as the initial PSQI score. Furthermore, selected samples sign an informed consent letter as a form of consent to engage in research. Geriatric patients who have been involved as research samples are given sleep hygiene education. After that, the randomization of 36 research samples was carried out to be divided into two groups that were given different treatments. A total of 18 study subjects were given acupuncture treatment and 18 others were given *sham* acupuncture treatment. In this study, both acupuncture and *sham* acupuncture interventions used three acupuncture points, including GV20 Baihui, HT7 Shenmen, SP6 Sanyinjiao, and MA-TF1 Shenmen sequentially presented in Figure 1, Figure 2, Figure 3, and Figure 4. Meanwhile, the difference between those interventions is that the acupuncture intervention was done by inserting a needle so that it penetrated the skin while *sham* acupuncture was done by giving a pricking sensation by applying plaster to the acupuncture point so that the needle did not penetrate the skin.

Outcome Measurements and Data Analysis

After being treated for eight therapy sessions, the final PSQI score of each study subject was calculated. After obtaining



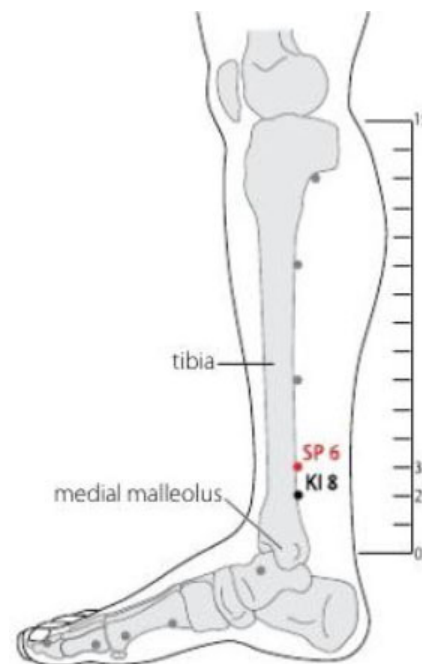
GV20

Figure 1. GV20 Baihui acupuncture point.



HT7

Figure 2. HT7 Shenmen acupuncture point.



SP6

Figure 3. SP6 Sanyinjiao acupuncture point.

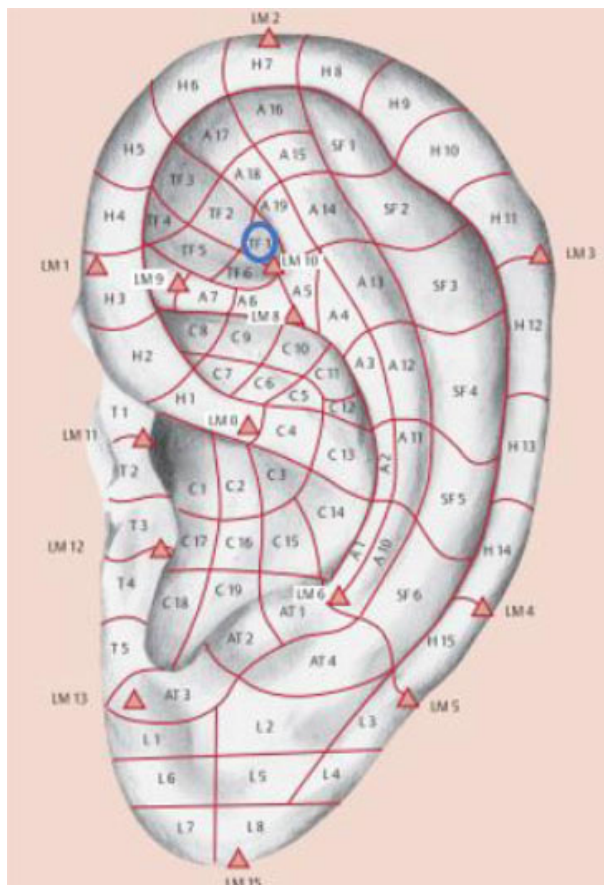


Figure 4. MA-TF1 Shenmen acupuncture point.

the initial and final PSQI data, data analysis was carried out using the T-Test to compare two groups of numerical variables that were normally distributed. Meanwhile, if the data is not normally distributed, the Mann-Whitney Test will be performed. The testing criteria in this study are that the two groups can be said to have significantly different averages if a p-value of < 0.05 is obtained. All data analysis was conducted using SPSS software v.20.0 for Windows (IBM, Armonk, NY, USA). Furthermore, reporting and presenting the results of data analysis are carried out.

RESULTS

As explained earlier, basically, this study involved 36 research subjects. However, one sample of each group was eliminated so that only 34 subjects managed to follow the research process to completion and analyzed. One subject in the acupuncture group refused therapy because he did not like the sensation of pricking acupuncture needles. Meanwhile, one subject in the *sham* acupuncture group was unable to continue therapy due to busyness. Therefore, a total of 17 patients were given acupuncture treatment and 17 were given *sham* acupuncture treatment.

Based on the results of descriptive statistical analysis, no significant difference was found between two groups on baseline demographic and clinical characteristics, including age, gender, education level, marital status, comorbidities,



Table 1. Baseline demographic and clinical characteristics of subjects for each group

Characteristic	Acupuncture group (n=17)	Sham acupuncture group (n=17)	p-Value
Age (years mean±SD)	71.24±5.652	70.76±4.191	0.785*
Gender (n [%])			0.714**
Male	5 (29.4%)	6 (35.3%)	
Female	12 (70.6%)	11 (64.7%)	
Education level (n [%])			0.954***
Junior high school	2 (11.8%)	1 (5.9%)	
Senior high school	7 (41.2%)	5 (29.4%)	
Diploma/college	8 (47.1%)	11 (64.7%)	
Marital status (n [%])			0.954***
Married	11 (64.7%)	8 (47.1%)	
Widower	0 (0%)	4 (23.5%)	
Widow	6 (35.3%)	5 (29.4%)	
Concomitant chronic disease (n [%])			
Diabetes mellitus	9 (52.9%)	8 (47.1%)	0.732**
Hypertension	14 (82.4%)	12 (70.6%)	0.688****
Heart disease	7 (41.2%)	7 (41.2%)	1.0**
Asthma or COPD	2 (11.8%)	3 (17.6%)	1.0****
Chronic pain	11 (64.7%)	11 (64.7%)	1.0**
Dyslipidemia	10 (58.8%)	14 (82.4%)	0.132**
History of stroke	2 (11.8%)	4 (23.5%)	0.656****
Kidney disease	5 (29.4%)	3 (17.6%)	0.688****
Body mass index (n [%])			0.954***
Underweight (<18.5)	2 (11.8%)	0 (0%)	
Normal (18.5-22.9)	7 (41.2%)	6 (35.3%)	
Overweight (23.00-24.9)	2 (11.8%)	5 (29.4%)	
Obese I (25.0-29.9)	3 (17.6%)	3 (17.6%)	
Obese II (≥ 30.0)	3 (17.6%)	3 (17.6%)	
Quality of life			0.122*****
EQ-5D-3L	0.768 (0.581-1.0)	0.693 (0.576-1.0)	0.844*
EQ-VAS	69.00±10.553	68.24±11.851	0.398****
Barthel ADL index			
Independent (20)			
Slight dependency (12-19)			1.0****
Geriatric depression scale			
Normal (0-4)	13 (76.5%)	12 (70.6%)	
Suggestive of depression (5-9)	4 (23.5%)	5 (29.4%)	
Mini mental state examination			
No cognitive impairment (24-30)	17 (100%)	17 (100%)	1.0****
Coffee drinking habit			0.785*
Yes	5 (29.4%)	4 (23.5%)	0.714**
No	12 (70.6%)	13 (76.5%)	

Notes: *Independent T-test; **Pearson Chi-square; ***Kolmogorov-Smirnov test; ****Fisher's Exact test; *****Mann-Whitney test

concomitant chronic diseases, body mass index, quality of life and functional status, and coffee drinking habit (Table 1).

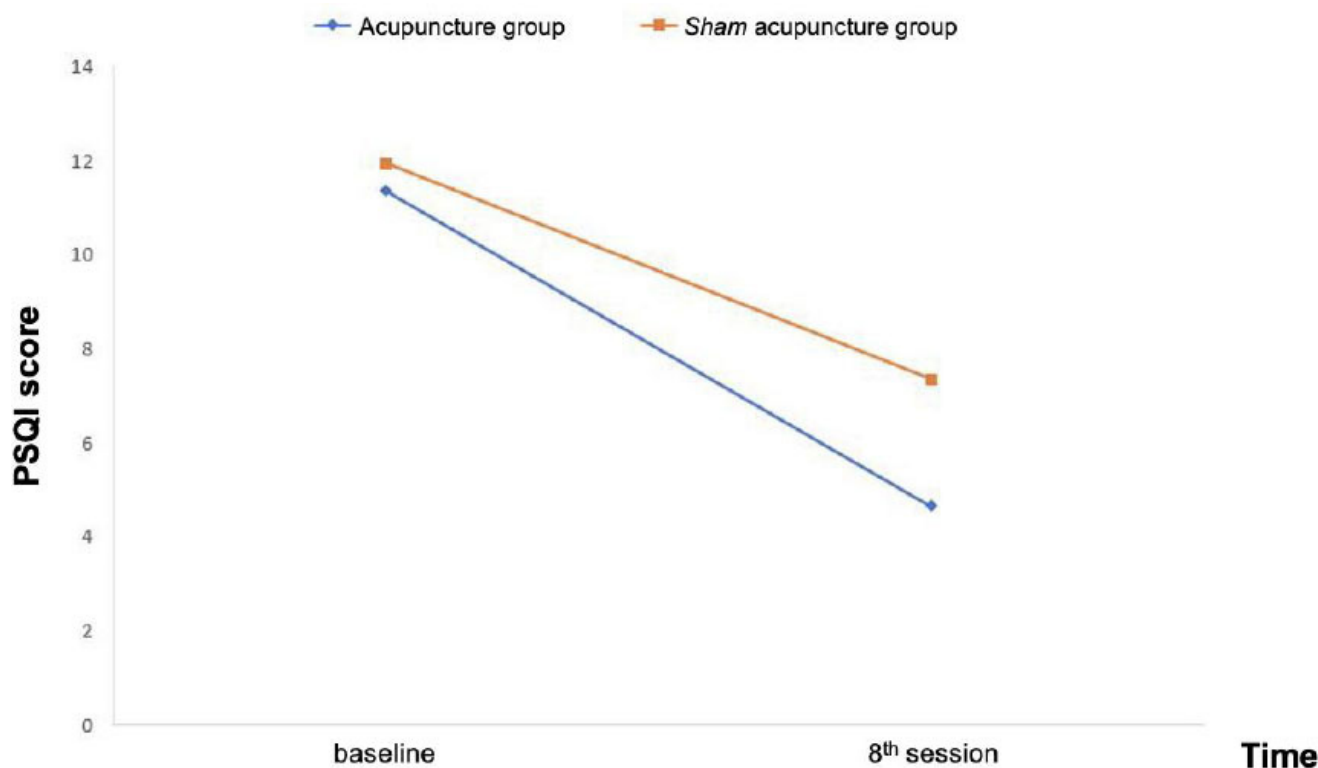
A comparative analysis of PSQI scores was carried out which resulted that the initial PSQI scores of the acupuncture and sham acupuncture groups were not significantly different ($p = 0.488$). Meanwhile, the final PSQI scores of the acupuncture group and sham acupuncture were significantly different ($p = 0.002$) where the acupuncture PSQI score of 4.65 was lower

than sham acupuncture of 7.35. In the acupuncture group, the average of initial and final PSQI scores were significantly different ($p < 0.001$) where the final PSQI score was lower at 4.65 compared to the initial PSQI score of 11.35. On the other hand, in the sham acupuncture group, the average of initial and final PSQI scores were also significantly different ($p < 0.001$) where the final PSQI score was lower at 7.35 compared to the initial PSQI score of 11.94.

**Table 2. The comparison of PSQI score**

	Acupuncture group (n=17)	Sham acupuncture group (n=17)	p-value
Initial PSQI score	11.35 (SD 2.621)	11.94 (SD 2.249)	0.488*
Final PSQI score	4.65 (SD 2.572)	7.35 (SD 1.935)	0.002*
P-value	<0.001**	<0.001**	
Initial and final PSQI score difference	6 (3.0-14.0)	4.5882 (2.0-8.0)	0.013***

Notes: *Independent T-test; **Paired T-test; ***Mann-Whitney test

**Figure 5.** Change of PSQI scores in two groups.

Furthermore, the difference between the two scores was compared and it was found that the difference of the initial and final PSQI scores in the acupuncture and sham groups were significantly different ($p = 0.013$) where the acupuncture group had a higher PSQI score difference of six compared to the sham group which is 4.59. It shows that acupuncture can provide a better and more significant improvement in sleep quality than sham acupuncture. This is the final analysis result that answered all of the research questions so that no ancillary analysis was conducted. The results of this data analysis are presented in Table 2 and Figure 5.

After the treatment had been conducted on the subjects, there were 5 subjects of the acupuncture group who complained pain during needle insertion. Minor bleeding after the needle was removed occurred on average once in 12 subjects and most commonly occurred at the MA-TF1 Shenmen ear acupuncture point. The bleeding stopped immediately after light pressure with 70% alcohol cotton.

Meanwhile, no effect was complained by subjects of the sham acupuncture group.

DISCUSSION

The results of the analysis of subject characteristics showed that elderly geriatric patients with female sex, BMI above normal, and married status suffered more from insomnia according to research conducted by Haseli et al.¹⁶ In addition, based on the research of Park et al.¹⁷ elderly patients with diverse chronic illnesses tend to experience insomnia. This is supported by the research of Kim et al.¹⁸ which results in the relationship between the illness suffered by the elderly and insomnia. In this case, diseases such as somatic pain, heart disease, dyslipidemia, and kidney disease are associated with insomnia. Meanwhile, Ogunbonde et al.¹⁹ found that hypertension and diabetes mellitus were not associated with insomnia while coffee-drinking habits associated with

insomnia were found in only a handful of elderly people.

To assess the quality of sleep of the subjects, a PSQI score that has been validated in Indonesian and consists of 19 questions answered by subjects ranging from 0 to 3 is used. In the PSQI assessment, there are 7 components assessed, including subjective sleep quality, sleep latency, sleep duration, habituation sleep efficiency, sleep disorders, use of sleeping pills, and daytime dysfunction. The total overall score is 0 to 21 where a score of 0 to 4 indicates good sleep quality, and a score of more than 5 indicates poor sleep quality. At the start of the study, there was no difference in PSQI scores in the acupuncture and *sham* acupuncture groups. However, after the 8th session, there was a significant decrease in PSQI scores and the acupuncture group had a higher PSQI score difference than *sham* acupuncture. This indicates that acupuncture has a significant effect on decreasing PSQI scores or improving sleep quality compared to *sham* acupuncture. This is in accordance with research conducted by Gao et al²⁰ which showed that the PSQI scores between the acupuncture and *sham* acupuncture groups were significantly different. Research Zuppa et al²¹ also provided similar results that the initial and final PSQI scores in the acupuncture group with SP6 Sanyinjiao, LI4 Hegu, ST36 Zusanli, LR3 Taichong, PC6 Neiguan, and EX-HN3 Yintang points were significantly different, while the *sham* acupuncture group was given superficial puncturing away from acupuncture points.

This study has limitations, including the patient recall bias, lack of exploration of confounding factors such as poor sleep hygiene and socio-economic status. Hence, for further study, researchers may consider measuring melatonin as a biomarker for insomnia, conducting research at multiple centers so it can represent the larger population, using sleep diaries to reduce recall bias, conducting research by considering double-blinded randomized clinical trial design with control to minimize bias risk, and assessing confounding factors that could affect patient sleep quality.

CONCLUSION

Acupuncture intervention in geriatric patients with insomnia was able to reduce PSQI scores more significantly than *sham* acupuncture. It means that acupuncture therapy is more effective for improving the sleep quality of geriatric patients suffering from insomnia than *sham* acupuncture. Thus, acupuncture therapy can be used as an alternative to nonpharmacological therapy in geriatrics with insomnia if standard therapy does not have a significant effect on improving sleep quality.

ACKNOWLEDGMENTS

The authors thank the head of the Cipto Mangunkusumo Hospital, physicians, from the medical

acupuncture department, internal medicine department, psychiatric department, and all the nurses at Cipto Mangunkusumo Hospital. The authors also express their gratitude to the participants of this study.

CONFLICT OF INTEREST

The author reports no conflicts of interest in this work.

ETHIC CONSIDERATION

This study was approved by Ethics Committee of the Faculty of Medicine, University of Indonesia (1173/UN2.F1/ETIK/2017). The study participants provided their written informed consent to participate in this study.

FUNDING

The authors received no financial support for the research, author- ship, and/or publication of this article.

AUTHOR'S CONTRIBUTIONS

GT, GR, HM, and AS responsible for conceptualization of the study. GT responsible for data collection. AMP, DR, FH, FS responsible for project administration. GT responsible for writing of the original draft. AGR, HM, and AS supervised the study. AMP, DR, FH, and FS responsible for reviewing and editing of the study. All authors approved the final manuscript.

REFERENCES

- Walston J. Aging. In: Durso SC, Bowker LK, Price JD, Smith SC, editors. Oxford American Handbook of geriatric medicine New York: Oxford University Press; 2010. p. 2-10.
- He W, Goodkind D, Kowal P. An aging world: 2015. Washington, DC; 2016.
- Gindin J, Shochat T, Chetrit A, et al. Insomnia in long-term care facilities: a comparison of seven European countries and Israel: The Services and Health for Elderly in Long Term care study. *Journal of the American Geriatrics Society*. 2014;62(11):2033-9.
- Kim WH, Kim BS, Kim SK, et al. Prevalence of insomnia and associated factors in a community sample of elderly individuals in South Korea. *International psychogeriatrics*. 2013;25(10):1729-37.
- Rodriguez JC, Dzierzewski JM, Alessi CA. Sleep problems in the elderly. *The Medical clinics of the North America*. 2015;99(2):431-9.
- Vitiello MV, Moe KE, Prinz PN. Sleep complaints cosegregate with illness in older adults: clinical research informed by and informing epidemiological studies of sleep. *Journal of psychosomatic research*. 2002;53(1):555-9.
- Carlson C, Merel SE, Yukawa M. Geriatric syndromes and geriatric assessment for the generalist. *The Medical clinics of North America*. 2015;99(2):263-79.
- McCall MV. Sleep in the elderly: burden, diagnosis, and treatment. *Primary care companion to the Journal of clinical psychiatry*. 2004;6(1):9-20.
- Kamel NS, Gammack JK. Insomnia in the elderly: cause, approach, and treatment. *The American journal of medicine*. 2006;110(6):463-9.
- Kay DB, Buysse DJ, Germain A, et al. Subjective-objective sleep discrepancy among older adults: associations with insomnia diagnosis and insomnia treatment. *Journal of sleep research*. 2015;24(1):32-9.



11. Sarris J, Byrne GJ. A systematic review of insomnia and complementary medicine. *Sleep medicine reviews*. 2011;15(2):99-106.14.
12. Dai J, Chiu HF, Xiang YT, et al. The prevalence of insomnia and its socio-demographic and clinical correlates in older adults in rural China: a pilot study. *Aging & mental health*. 2013;17(6):761-5.
13. World Health Organization. Acupuncture: review and analysis of reports on controlled clinical trials. Geneva: World Health Organization; 2003.
14. Shergis JL, Ni X, Jackson ML, et al. A systematic review of acupuncture for sleep quality in people with insomnia. *Complementary therapies in medicine*. 2016;26:11-20.
15. Shanghai College of Traditional Medicine. Points. In: O'Connor J, Bensky D, editors. *Acupuncture A Comprehensive Text*. Chicago: Eastland Press; 1981. p. 141-262.
16. Haseli-Mashhadi N, Dadd T, Pan A, et al. Sleep quality in middle-aged and elderly Chinese: distribution, associated factors and associations with cardio-metabolic risk factors. *BMC public health*. 2009;9:130.
17. Park SU, Lee SY, Baek YH, et al. Intradermal acupuncture on shen-men and nei-kuan acupoints improves insomnia in stroke patients by reducing the sympathetic nervous activity: a randomized clinical trial. *The American journal of Chinese medicine*. 2009;37(6):1013-21.
18. Kim WH, Kim BS, Kim SK, Chang SM, Lee DW, Cho MJ, et al. Prevalence of insomnia and associated factors in a community sample of elderly individuals in South Korea. *International psychogeriatrics*. 2013;25(10):1729-37.
19. Ogunbode AM, Adebuseye LA, Olowookere OO, et al. Factors associated with insomnia among elderly patients attending a geriatric centre in Nigeria. *Current gerontology and geriatrics research*. 2014;2014:780535.
20. Gao J, Liu Y, Feng H, et al. Effect of soothing-liver and nourishing-heart acupuncture on early selective serotonin reuptake inhibitor treatment onset for depressive disorder and related indicators of neuroimmunology: a randomized controlled clinical trial. *Journal of traditional Chinese medicine = Chung i tsa chih ying wen pan*. 2015;35(5):507-13.
21. Zuppa C, Prado CH, Wieck A, et al. Acupuncture for sleep quality, BDNF levels and immunosenescence: a randomized controlled study. *Neuroscience letters*. 2015;587:35-40.



This work is licensed under a
[Creative Commons Attribution 4.0
 International License](https://creativecommons.org/licenses/by/4.0/).