

Effects of Foot Reflexology on Fatigue, Sleep and Pain: A Systematic Review and Meta-analysis

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Purpose: The purpose of this study was to evaluate the effectiveness of foot reflexology on fatigue, sleep and pain. **Methods:** A systematic review and meta-analysis were conducted. Electronic database and manual searches were conducted on all published studies reporting the effects of foot reflexology on fatigue, sleep, and pain. Forty four studies were eligible including 15 studies associated with fatigue, 18 with sleep, and 11 with pain. The effects of foot reflexology were analyzed using Comprehensive Meta-Analysis Version 2.0. The homogeneity and the fail-safe N were calculated. Moreover, a funnel plot was used to assess publication bias. **Results:** The effects on fatigue, sleep, and pain were not homogeneous and ranged from 0.63 to 5.29, 0.01 to 3.22, and 0.43 to 2.67, respectively. The weighted averages for fatigue, sleep, and pain were 1.43, 1.19, and 1.35, respectively. No publication bias was detected as evaluated by fail-safe N. Foot reflexology had a larger effect on fatigue and sleep and a smaller effect on pain. **Conclusion:** This meta-analysis indicates that foot reflexology is a useful nursing intervention to relieve fatigue and to promote sleep. Further studies are needed to evaluate the effects of foot reflexology on outcome variables other than fatigue, sleep and pain.

Key words: Systematic review, Foot reflexology, Fatigue, Sleep, Pain

INTRODUCTION

Alternative medicine is used to improve the symptoms of diseases and pain with the healing power of nature and to reinforce the immune system and recuperative power of the body. In other words, alternative medicine may be used to observe and harmonize physical, mental, social, and environmental aspects in totality in patients (Oh, 1994). In recent years, the popularity of alternative medicine has grown due to the increasing popularity of holistic approaches to health that emphasize the integration of body, mind, and spirit along

with physical symptoms in improving health care and well-being (Im & Nam, 2005). Therefore, patients with chronic diseases that are not completely healed by modern medicine are increasingly using complementary and alternative medicine in the process of seeking other treatments (Lee & Park, 1999).

Because of the growing popularity of complementary and alternative medicine as holistic approaches to health, many reports have demonstrated that medical services utilizing both western and traditional medical practices have positive effects on the psychological stability of subjects (Cho, 1999). Meridian massages can be made more

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systematic by combining the meridian concept of oriental medicine with massage and has been applied to treat a variety of diseases beyond the scope of general massage (Lee, 1992). Consequently, many medical practitioners have begun to adopt more positive attitudes toward alternative medicine (Eisenberg, Kessler, & Foster, 1993).

Recently, nursing interventions involving various aspects of alternative are better understood and accepted in practice. Many studies have been conducted to verify its effects and assess its role as an intervention (Norred, Zamudio, & Palmer, 2000). It is reported that 32%-41% of chronic patients in Western Europe and 60%-75% of patients in Korea use alternative medicine (Choi, Jeong, & Choi, 1998; Foltz et al., 2005).

Foot reflexology therapy has a long history; it appeared in an ancient tomb mural in Egypt around 2330 B.C. and was organized by William Hope Fitzgerald, an American doctor, in 1917 (Kim, 1999). Because it is free from side effects, easy to learn and perform, and requires only a little knowledge on meridian, foot reflexology has become popular in the general public (Yang, 2005). It is well acknowledged that foot reflexology therapy effectively facilitates blood and lymph circulation which accelerate the excretion of waste, soften and stabilize the movement of muscle, joints, and tendons, reinforce muscle strength, and promote relaxation (Kim, 2001).

Meta-analysis is a statistical method commonly used to objectively generalize parameters and to derive systematic information from many studies on same topic studied over a long periods of time. It has the advantage of obtaining reliable and useful information and of suggesting evidence by systematic analysis and national interpretation (Song, 1998). The meta-analysis has been applied to many nursing fields for it is very useful in summarizing the effects of nursing interventions (Kim, 2009; Kim, 2011; Min, 2011).

Since systematic consideration for meta-analysis requires rigorous methodological protocols, possible deviations and biases across all phases must be considered to obtain reliable and accurate conclusions (Scanlin, 2006). Conclusions drawn from such rigorous process provide an excellent evidence for clinical practice (Evans, 2001).

A few meta-analyses evaluating the effects of foot reflexology have been conducted (Kim, 2009; Kim, 2011; Min, 2011). Kim (2009) performed a meta-analysis to evaluate the effects of foot reflexology on 14 outcome variables including fatigue, sleep, and pain. A meta-analysis was conducted to evaluate the effects of foot reflexology on cancer patients (Kim, 2011), and another meta-analysis was conducted to

evaluate the effects on pain among cancer patients (Min, 2011). However, Kim (2009)'s study did not perform a systematic review or a process for assessing the methodological quality of studies included in the analysis.

The purpose of this study was to systematically review the effects of foot reflexology on fatigue, sleep, and pain. The specific objectives of this study were a) to analyze the effects of foot reflexology on fatigue, sleep, and pain and b) to explore the differences due to various characteristics of the subjects and the intervention. The results of this study may provide useful evidence for developing an efficient model of a foot reflexology program.

METHODS

1. Research design

This study is a systematic review and meta-analysis of intervention studies to evaluate the effects of foot reflexology on fatigue, sleep, and pain. In this study, foot reflexology is an application of pressure to specific points on the foot. It consists of 3 phases including a relaxation phase, a massage phase, and a finishing phase (Choi, 2002).

2. Inclusion and exclusion criteria for consideration of studies for review

Studies satisfying the following criteria were included for the analysis: a) an intervention study utilizing foot reflexology; b) a randomized controlled trial (RCT) or nonequivalent control group pretest-posttest study with a no intervention group as a control; c) a study with homogeneity of the baseline characteristics between the experimental and control groups; d) a study examining the effects of foot reflexology on fatigue, sleep, or pain; e) a study with the mean and standard deviations, the sample size of experimental and control groups, or t-values to calculate effects; and f) a study considered to be appropriate for meta-analysis evaluated by using a patient, intervention, comparison and outcome (PICO) chart and by an evaluation checklist for methodological quality (Higgins & Green, 2008). If an article was published from a thesis or dissertation, the thesis or dissertation was selected over published articles to prevent duplication and to reduce publication bias.

3. Search and selection process of studies

1) Search strategy

Although meta-analysis is not affected by published language (Moher, Liberati, Tetzlaff, Altman, & PRISMA Group, 2009), the search was limited to studies published in Korean and in English and available to full-text search. The literature searches of electronic databases (e.g., MEDLINE, CINAHL, SCOPUS, PROQUEST, Science Direct, Cochrane Library, and Google Scholar) were performed using the keywords 'reflexology', 'foot reflex', 'foot massage' and 'intervention'. To search Korean studies, paper published journals and electronic databases such as the Korean Studies Information Service System (<http://search.koreanstudies.net/>), the National Assembly Digital Library (www.nanet.go.kr), and the Research and Information Sharing Service (<http://www.riss.kr/index.do>), were searched using 'foot reflexology', 'Bal-massage', 'Bal-bansa', 'foot reflex', 'foot reflexology massage', 'reflexology', 'foot reflex', 'foot massage' and 'intervention' as keywords. Furthermore, the reference lists of previous reviewed articles and eligible studies were hand searched to locate other potentially eligible studies. The year of publication was not limited but had to be published before 2010 because data collection for this study was conducted from May 25, 2010 to March 7, 2011.

2) Selection process of studies

- (1) Duplicate studies were excluded using EXCEL database by comparing the title, the author, and year published.
- (2) Inappropriate studies (e.g., one-group studies, self-performed reflexology) were excluded by examining the title and the abstract.
- (3) Studies not including fatigue, sleep, or pain as an outcome variable were excluded by examining the title and the abstract.

4. Systematic review of the included studies

The methodological quality of the included studies was assessed as follows:

- 1) For each of the remaining potentially relevant study, two independent reviewers assessed the methodological quality of each study using the PICO chart in the Cochrane handbook (Higgins & Green, 2008). The number of subjects, subject characteristics (condition, important characteristics, demographic factor, setting, criterion, etc), intervention (exposure, diagnostic procedure, prognostic factor, and

therapeutic intervention), comparison, study length, outcome measures, effect size, funding, and main conclusions were analyzed. When the process was completed 21 studies that did not meet the inclusion criteria or definition of foot reflexology were excluded.

- 2) Since there was no methodology checklist for non-RCT, an evaluation checklist for assessing the methodological quality of RCT (Higgins & Green, 2008) was modified. The methodology checklist for RCT consisted of 10 items for internal validity including 3 items for overall assessment of the study and 9 items for description of the study. These 9 items were excluded because they were already included in PICO. Among the items for internal validity, 3 items (random assignment, concealment, and blind), which were irrelevant for non-RCT, were also excluded.

Internal validity (study subject, definition of concept, homogeneity between two groups, intervention identity, accuracy of measurement, attrition rate, equality of intervention, intent to treat, and site difference) were categorized into 6 levels including 'well covered', 'adequately addressed', 'poorly addressed', 'not addressed', 'not reported', and 'not applicable'. Three items for overall evaluation (minimization of the bias, internal validity, external validity) were rated as either '+', '+', or '-'. If necessary, special considerations were marked separately for discussion and any discrepancies in evaluation of methodological quality any discrepancies were resolved by discussion and consensus of other authors.

5. Data synthesis and analysis

Prior to synthesis of effect sizes, a homogeneity test was conducted. Effect sizes and 95% confidence intervals were calculated for each outcome variable both for the entire studies and for subgroups of studies. Statistical analysis was performed using Comprehensive Meta-Analysis (CMA) version 2.0.

1) Decision of sign for effect size

It was important to keep the sign of the value to be consistent with the direction of change of the outcome variable. The signs were assigned as follows: A lower score indicated a positive effect (+) on fatigue and pain and a higher score indicated a positive effect (+) on sleep.

2) Homogeneity test

A test for the homogeneity of effect size (d) across studies was con-

ducted and outliers that impaired homogeneity were excluded (Oh, 1994). Q statistics were used to test the homogeneity of the effect sizes. Homogeneity was accepted when the *p*-value was greater than .05. The combined effect size was calculated for the studies when homogeneity was accepted. I^2 were used to test the heterogeneity. If above 50% or 75%, it is considered heterogeneous or highly heterogeneous, respectively. If I^2 is below 25%, it is considered homogeneous (Nikolaos, Evangelos, & John, 2008).

3) Effect size

For each outcome variable, the standardized mean difference between the experimental and control groups was calculated for each study, based on the mean and standard deviation before and after the treatment, and the number of subjects in the two groups. The combined effect size was estimated using a weighted mean. According to Cohen (1977), effect size $d = 0.80$ was interpreted as a 'large-sized effect' indicating that the mean for the experimental group was 0.8 times larger than the control group. An effect size greater than or equal to 0.50 was interpreted as a 'medium-sized effect', and an effect size greater than or equal to 0.20, 'small-sized effect'.

It is typical to report the combined effect size when homogeneity was accepted. However, according to Cohen (1977), the overall summary of studies is meaningful even when the effect sizes are not homogeneous. Therefore, the combined effect size in this study is presented although the homogeneity was not accepted.

4) Assessment of publication bias

Funnel plots and fail-safe N were used to assess possible publication bias. When the effect sizes were distributed evenly in a triangular shape and symmetric about combined effect size in the funnel plot, publication bias was not considered to be present. When the effect sizes were not evenly distributed, imputation was conducted using the trim and fill method. Imputation involves inserting studies that may not have been published due to small effect sizes. When the combined effect size was not significantly changed after imputation, publication bias was not considered to be present (Sutton, Duval, Tweedie, Abrams, & Jones, 2000).

The combined effect size is generally significant because meta-analysis is conducted using published studies. The combined effect size can be changed by the number of unpublished studies possibly due to non-significant results. The fail-safe N is the number of un-

published studies that can convert the results of the meta-analysis (Song, 1998). In other words, it is an index that indicates the number of unpublished studies that would be required to reduce the observed mean effect size below the level of significance. Whenever the size of the fail-safe N is large, the results of the meta-analysis are considered to be credible because it would take an improbable number of unpublished studies to decrease the effects. However, whenever the size of the fail-safe N is small, the results of the meta-analysis are not considered to be credible because inclusion a small number of unpublished studies can change the results of the meta analysis. In this study, the criteria of trivial standardized mean differences and standardized mean differences in missing studies were chosen to be 0.2 and 0.0, respectively.

RESULTS

1. Selection of eligible studies

A total number of 396 published studies (382 studies in Korea and 14 studies in English) evaluating the effects of foot reflexology on fatigue, sleep, and pain were found. There was no limit in terms of length and number of foot reflexology because it was found from a preliminary review and a discussion with experts that the foot reflexology may be effective even with only one application.

When the exclusion was completed, 44 studies were selected, including 15 studies for fatigue, 18 studies for sleep, and 11 studies for pain. Data related to subjects, duration, frequency, and time per session for foot reflexology were collected. The selection of eligible studies was conducted based on the PRISMA 2009 flow diagram (Moher et al., 2009) and is presented in Figure 1.

2. Characteristics of the eligible studies

Of the 100 studies that evaluated the effects on fatigue, 15 studies were selected including 9 master theses and 6 peer-reviewed journal articles (Figure 1). The characteristics of the studies are presented in Table 1. Two types of subjects were involved in the studies: 8 patients and 7 lay people. The most common duration of massage therapy was from 1 week to 3 weeks ($n = 8$), and patients typically received 3 to 8 massages. Sessions typically lasted 30 to 50 minutes per massage ($n = 12$). Among the 15 studies, 12 used a measurement tool known as

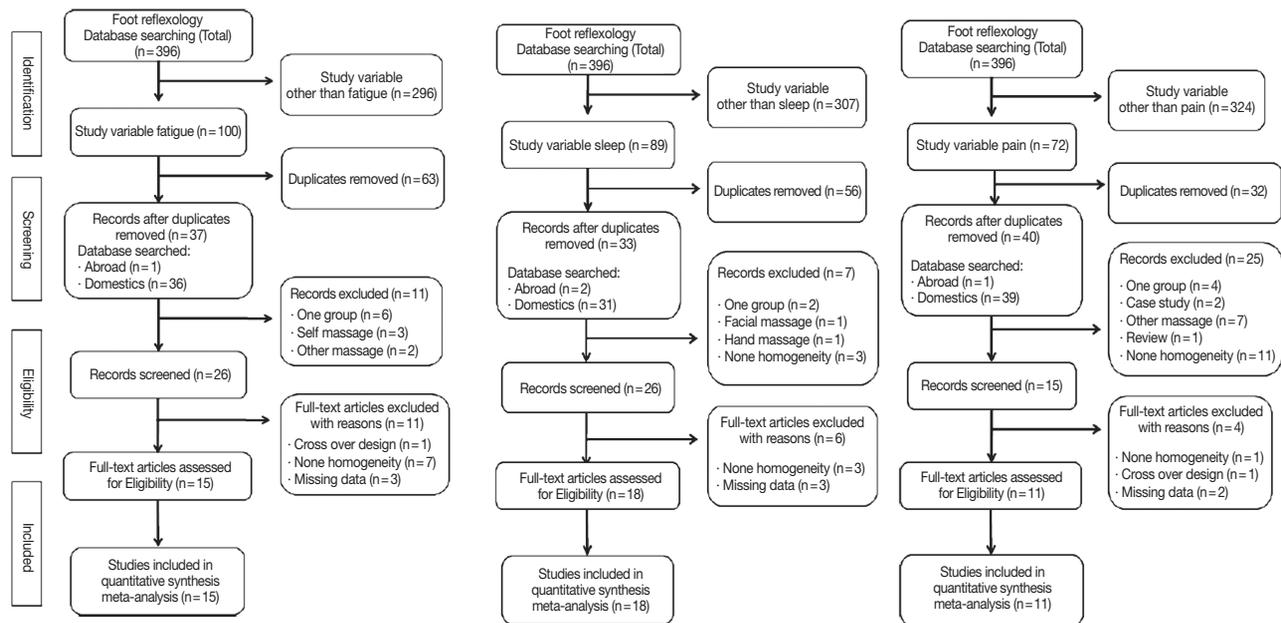


Figure 1. Foot reflexology: Flow diagram based on PRISMA (Moher et al., 2009).

the 'Awareness on Fatigue Scale' from the Japanese Labor Science Institute.

Of the 89 studies that evaluated the effects on sleep, 18 studies were selected including 8 master theses, 3 doctoral dissertations, and 7 peer-reviewed journal articles (Figure 1). The characteristics of the studies are presented in Table 1. The subjects of 7 studies were patients, and the subjects of 11 were lay people. The most common duration of massage therapy was from 1 to 3 weeks (n=10). Among the 18 studies, 7 studies applied 1 to 4 massages, and 9 applied over 10 massages. Massage sessions typically lasted 30 to 50 minutes (n=14). As a measurement tool 8 studies used the 'Sleep Satisfaction Scale' and 8 used the Verran and Synder-Halpern Sleep Scale (VHS).

Of the 72 studies that evaluated the effects on pain, 11 studies were selected including 7 master theses, a doctoral dissertation, and 3 peer-reviewed journal articles (Figure 1). The characteristics of the studies are presented in Table 1. The subjects of 8 studies were patients and the subjects of 3 studies were lay people. Among the 11 studies, 6 studies applied massage for 5 to 6 days, and 5 studies applied massage for longer than 7 days. Patients typically received 10 massages (n=9). Massage sessions typically lasted 30 minutes for 7 studies and 20 minutes for 5 studies. The most commonly used measurement tool was VAS.

3. Meta-analysis of foot reflexology on fatigue, sleep and pain

The results of meta-analyses for each dependent variable are shown in Table 2. The effect sizes of the 15 studies that evaluated the effects of foot reflexology on fatigue ranged from 0.63 to 5.29, and all 15 studies exhibited an above medium effect size. In a homogeneity test, the overall effect size (100%) was not homogenous ($Q=104.63$, $p<.001$, $I^2=86.63\%$), and the combined effect size was 1.43. In a Funnel plot analysis, 2 studies were filled, but there was only a small difference in the effect size (1.51). The fail-safe N was 93.

The effect sizes of the 18 studies that evaluated the effects of foot reflexology on sleep ranged from 0.01 to 3.22. The effect sizes of two studies, So et al (2004) and Kim (2007), were not as effective (0.01 and 0.02, respectively). In the Song's study (2004), the effect size was small (0.22). The other studies reported above average effect sizes. The effect sizes were not homogenous ($Q=115.96$, $p<.001$, $I^2=85.34\%$), and the combined effect size was 1.19. In a Funnel plot analysis, 1 study was filled, but there was only a minimal change in the combined effect size (1.14). The fail-safe N was 89.

The effect sizes of 11 studies that evaluated the effects of foot reflexology on pain ranged from 0.43 to 2.67. The effect sizes were large in all of the studies except in 1 (Kyong's study, 2006). However, the effect sizes were not homogenous ($Q=24.50$, $p<.006$, $I^2=59.19\%$), and the

Table 1. Characteristics of Foot Reflexology Intervention Studies included in Meta-Analysis

Study Variable	ID	Type of Subject	Sample size		Intervention period Weeks/Number of sessions/Min	Instrument	Source	Direction of effect	RCT
			Exp. (n)	Con. (n)					
Fatigue	2	Students	20	20	4W/ 8/ 50	JF	Master's	Increase	No
	3	Patients	18	16	6W/ 12/ 40	JF	Journal	Increase	No
	4	Patients	20	20	2W/ 8/ 30	JF	Master's	Increase	No
	9	Elders	30	29	1W/ 3/ 44	JF	Master's	Increase	No
	10	Elders	25	25	1W/ 3/ 45	JF	Master's	Increase	No
	12	Patients	30	30	1W/ 5/ 20	PI	Master's	Increase	No
	16	Patients	20	20	2W/ 6/ 30	JF	Master's	Increase	No
	18	Patients	17	17	6W/ 12/ 50	JF	Journal	Increase	No
	19	Nurses	20	20	2W/ 5/ 30	JF	Master's	Increase	No
	24	Women	20	20	6W/ 12/ 40	JF	Journal	Increase	No
	25	Patients	29	30	5W/ 10/ 60	JF	Master's	Increase	No
	28	Nurses	16	13	2W/ 5/ 30	JF	Master's	Increase	No
	29	Elders	30	29	3D/ 3/ 44	JF	Journal	Increase	No
	32	Patients	19	17	2D/ 2/ 25	VAS	Journal	Increase	No
34	Patients	18	16	1W/ 5/ 40	PI	Journal	Increase	No	
Sleep	6	Elders	20	18	1W/ 3/ 40	SH	Master's	Increase	No
	7	Elders	20	20	4W/ 8/ 30	Oh	Journal	Increase	No
	9	Elders	30	29	1W/ 3/ 44	Oh	Master's	Increase	No
	10	Elders	25	25	1W/ 3/ 45	Oh	Master's	Increase	No
	13	Patients	20	20	1W/ 2/ 20	SH	Master's	Increase	No
	15	Elders	20	20	3W/ 10/ 35	SH	Master's	Increase	No
	17	Patients	19	18	2W/ 12/ 30	SH	Master's	No diff	No
	18	Patients	17	17	6W/ 12/ 50	Oh	Journal	Increase	No
	20	Elders	26	25	5W/ 10/ 40	Oh	Doctoral	Increase	No
	22	Elders	11	11	6W/ 12/ 30	Oh	Master's	Increase	No
	23	Elders	18	18	2W/ 14/ 33	Oh	Master's	Increase	No
	25	Patients	29	30	5W/ 10/ 60	VAS	Doctoral	Increase	No
	26	Patients	29	30	5W/ 10/ 60	VAS	Journal	Increase	No
	27	Woman	32	33	1W/ 5/ 30	SH	Journal	Increase	No
29	Elders	30	29	1W/ 3/ 44	SH	Journal	Increase	No	
30	Patients	15	15	2D/ 2/ 30	SH	Journal	Increase	No	
31	Elders	25	25	2W/ 12/ 30	Oh	Doctoral	Increase	No	
32	Patients	19	17	2D/ 2/ 25	SH	Journal	No diff	No	
Pain	1	Woman	21	20	4W/ 12/ 30	WOMAC	Doctoral	Decrease	No
	5	Patients	17	17	1W/ 2/ 20	VAS	Master's	Decrease	No
	8	Patients	16	12	1D/ 1/ 20	VAS	Master's	Decrease	No
	11	Patients	14	15	1D/ 2/ 20	VAS	Master's	Decrease	No
	14	Patients	20	20	3D/ 3/ 30	VAS	Journal	Decrease	No
	17	Patients	19	18	4W/ 12/ 30	VAS	Master's	Decrease	No
	21	Elders	18	18	4W/ 8/ 30	VDS	Master's	Decrease	No
	22	Elders	11	11	6W/ 12/ 30	VAS	Master's	Decrease	No
	30	Patients	15	15	2D/ 2/ 30	VDS	Journal	Decrease	No
	33	Patients	30	31	3D/ 3/ 20	VAS	Journal	Decrease	No
	35	Patients	22	21	5D/ 5/ 30	VDS	Master's	Decrease	No

Exp. = Experimental group; Cont. = Control group; W = Weeks; D = Days; Weeks = Duration massages were applied; Min = Time per massage; JF = Japanese labor science institute(subjective symptom) of fatigue; VAS = Visual analogue scale; PI = Piper (1987); SH = Synder-Halpern & Verran (1987); Oh = Oh, Song & Kim (1998); Kim = Kim (1984); FAI = Fatigue assessment instrument; VDS = Numerical visual descriptor scale; RCT = Randomised controlled trial; WOMAC = Korean version of Western Ontario MacMaster University Oestoarthritis index questionnaire.

Table 2. Homogeneity, Mean Effect Size and Fail-Safe N of Foot Reflexology

ID	Author (s) name (yr)	Fatigue d (SD)	Sleep d (SD)	Pain d (SD)
1	An (2006)			2.10 (0.39)
2	Bae (2000)	4.54 (0.60)		
3	Cho & Park (2004)	1.31 (0.38)		
4	Choi (2002)	1.97 (0.39)		
5	Han (2001)			1.37 (0.38)
6	Han (2004)		0.98 (0.34)	
7	Im & Nam (2004)		0.96 (0.33)	
8	Jang (2001)			0.90 (0.40)
9	Jang (2003)	0.82 (0.27)	1.26 (0.29)	
10	Jin (2005)	1.08 (0.30)	2.56 (0.38)	
11	Kang (2003)			1.15 (0.40)
12	Kim (2004)	1.62 (0.30)		
13	Kim (2003)		0.86 (0.33)	
14	Kim & Park (2002)			1.37 (0.35)
15	Kim (2007)		0.02 (0.32)	
16	Kim (2006)	1.69 (0.37)		
17	Kyong (2006)		0.74 (0.34)	0.43 (0.33)
18	Kwon & Kwon (2005)	1.05 (0.37)	0.85 (0.36)	
19	Lee (2001)	1.59 (0.36)		
20	Lee (2006)		3.22 (0.51)	
21	Lee 1 (2008)			1.71 (0.50)
22	Lee 2 (2008)		1.02 (0.32)	1.59 (0.38)
23	Lee 1 (2006)		0.77 (0.29)	
24	Lee 2 (2006)	0.95 (0.33)		
25	Lee (2003)	5.29 (0.55)	2.67 (0.36)	
26	Lee & Song (2005)		2.67 (0.36)	
27	Li et al. (2009)		1.86 (0.30)	
28	Min (2001)	2.60 (0.51)		
29	Min (2007)	0.63 (0.27)	1.25 (0.29)	
30	Park, Yoo & Lee (2006)		1.90 (0.44)	2.67 (0.50)
31	Song (2004)		0.22 (0.28)	
32	So et al. (2004)	1.47 (0.38)	0.01 (0.33)	
33	Tasy et al. (2008)			0.80 (0.27)
34	Yang (2005)	0.99 (0.33)		
35	Yoo (2003)			1.43 (0.44)
		Homo Q (p): 104.63 (<.001) I ² : 86.62% d̄ ± SD (95% C.I.): 1.43 ± 0.08 (1.50 1.61) Nfs: 93	Homo Q (p): 115.96 (<.001) I ² : 85.34% d̄ ± SD (95% C.I.): 1.19 ± 0.08 (1.03 1.34) Nfs: 89	Homo Q (p): 24.50 (.006) I ² : 59.19% d̄ ± SD (95% C.I.): 1.35 ± 0.18 (1.01 1.70) Nfs: 60

Homo Q (p) = Homogeneity test Q (p), d̄ ± SD = Mean ES, Nfs = Fail-safe N

combined effect size was 1.35. In a funnel plot, the distribution of the effect sizes was symmetric. The fail-safe N was 60.

4. Meta-analysis of foot reflexology by subject characteristics and by intervention time

Subjects were categorized into patients and lay people (Table 3). Out of 15 studies on fatigue, the effect sizes of 8 studies on patients were homogeneous ($Q = 7.56$, $p = .373$, $I^2 = 7.4\%$). The combined effect size was 1.37 (95% CI: 1.13, 1.61). Publication bias was not found, and the fail-safe N was 47. Of the 7 studies on lay people, the effect sizes of two studies including Lee's study (2003) and Bae's study (2000) were 5.29 and 4.54, respectively. These were very different from other studies, and possible bias was found in funnel plot. Therefore, these two studies were excluded from the analysis (Figure 2). The effect sizes of the remaining 5 studies were moderately heterogeneous ($Q = 9.03$, $p = .060$, $I^2 = 56.70\%$), and the combined effect size was 1.04 (95% CI: 0.76, 1.32). The fail-safe N was 19.

Among 18 studies on sleep, the subjects of 7 studies were patients. The effect size was not homogeneous ($Q = 52.29$, $p < .001$, $I^2 = 88.53\%$), and the combined effect size was 1.31 (95% CI: 1.05, 1.57) (Table 3). The distribution of the effect sizes was not symmetric about the mean in the funnel plot. Therefore, the trim and fill method was adopted, but the combined effect size was not changed after imputation (Figure 2). The fail-safe N was 39. The effect sizes of 11 studies on lay people were not homogeneous ($Q = 22.13$, $p = .01$, $I^2 = 54.81\%$), and the combined effect size was 1.09 (95% CI: 0.90, 1.28). The fail-safe N was 49. The distribution of the effect sizes about the mean was symmetric in the funnel plot.

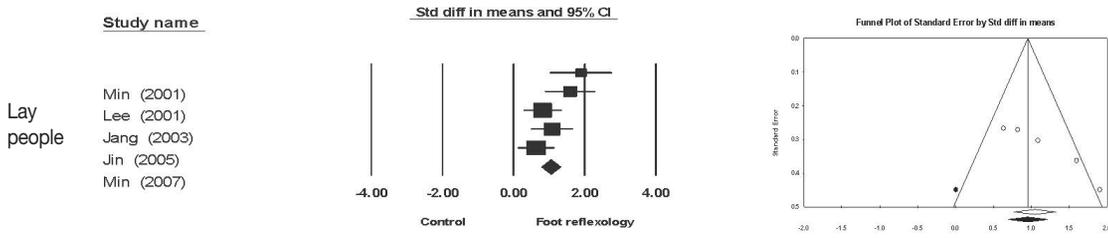
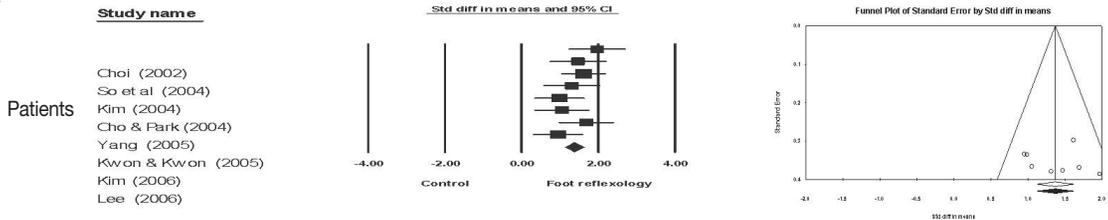
Of the 11 studies that measured the effects of foot reflexology on pain, the effect sizes of 8 studies on patients were homogeneous ($Q = 13.69$, $p = .57$, $I^2 = 48.87\%$). The combined effect size was 1.16 (95% CI: 0.81, 1.51) (Table 3). The fail-safe N was 29. The distribution of the effect sizes was not symmetric about the mean in the funnel plot. Therefore, the trim and fill method was adopted, but the combined effect size was not changed after imputation (Figure 2). The effect sizes of 3 studies on lay people were homogeneous ($Q = 0.91$, $p = .633$, $I^2 = 0\%$), and the combined effect size was 1.81 (95% CI: 1.34, 2.28). The fail-safe N was 25. The two sides of the funnel plot were similar (Figure 2).

Since the circulation time of meridian is reported to be 28 minutes (Jeong, 2006), the studies were classified as either more than 30 min-

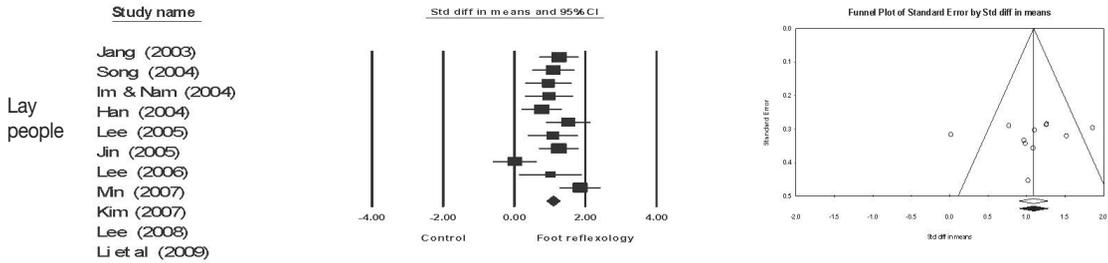
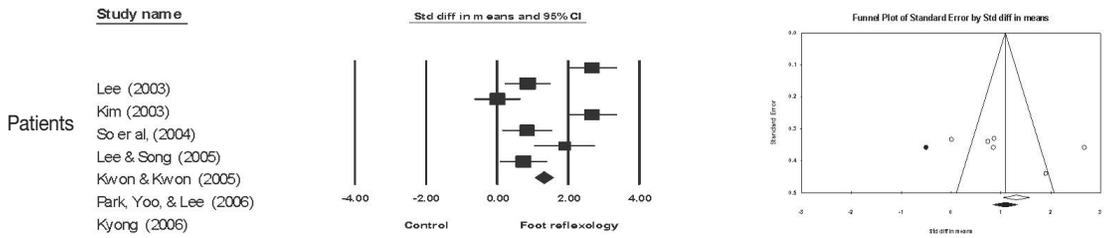
Table 3. Comparison of Effect Sizes between Patients and Lay People: Fatigue, Sleep & Pain

Study Variable	Author(s) name	Effect size (SD)	Weight (%)	Weighted mean	95% CI	Z (p)	Q (p)	I ² (%)	N _{fs}
Fatigue									
Patients	Choi (2002)	1.97 (0.39)	10.40						
	So et al. (2004)	1.47 (0.38)	10.91						
	Kim (2004)	1.62 (0.30)	17.45						
	Cho & Park (2004)	1.31 (0.38)	10.76						
	Yang (2005)	0.99 (0.33)	13.75	1.37	1.13	11.02	7.56	7.4	47
	Kwon & Kwon (2005)	1.05 (0.37)	11.52		1.61	(<.001)	(.373)		
	Kim (2006)	1.69 (0.37)	11.36						
	Lee (2006)	0.95 (0.33)	13.86						
			100%						
Lay People	Min (2001)	0.85 (0.39)	12.49						
	Lee (2001)	1.59 (0.36)	14.39						
	Jang (2003)	0.82 (0.27)	25.81	1.04	0.76	7.45	9.03	55.70	19
	Jin (2005)	1.08 (0.30)	20.67		1.31	(<.001)	(.060)		
	Min (2007)	0.63 (0.27)	26.64						
			100%						
Sleep									
Patients	Lee (2003)	2.67 (0.36)	14.08						
	Kim (2003)	0.86 (0.33)	16.54						
	So et al. (2004)	0.01 (0.33)	16.22						
	Lee & Song (2005)	2.67 (0.36)	14.08						
	Kwon & Kwon (2005)	0.85 (0.36)	14.10	1.31	1.05 1.57	9.74 (<.001)	52.29 (<.001)	88.53	39
	Park, Yoo & Lee (2006)	2.28 (0.47)	9.35						
	Kyong (2006)	0.74 (0.34)	15.64						
			100%						
Lay People	Jang (2003)	1.26 (0.29)	11.36						
	Song (2004)	1.10 (0.30)	10.02						
	Im & Nam (2004)	0.96 (0.33)	8.27	1.09	0.90	11.34	22.13	54.81	49
	Han (2004)	0.98 (0.34)	7.81		1.28	(<.001)	(.01)		
	Lee (2005)	0.77 (0.29)	10.96						
	Jin (2005)	1.52 (0.32)	8.96						
	Lee (2006)	3.22 (0.51)	7.24						
	Min (2007)	1.25 (0.29)	11.17						
	Kim (2007)	0.02 (0.45)	9.23						
	Lee (2008)	1.02 (0.45)	4.50						
Li et al. (2009)	1.85 (0.30)	10.49							
			100%						
Pain									
Patients	Han (2001)	1.36 (0.38)	10.84						
	Jang (2001)	0.90 (0.40)	9.79						
	Kim & park (2001)	1.37 (0.35)	12.71						
	Kang (2003)	1.15 (0.40)	9.75						
	Yoo (2003)	1.43 (0.34)	13.42	1.16	0.81 1.51	8.90	13.69	48.87	29
	Kyong (2006)	0.43 (0.33)	14.18			(<.001)	(.057)		
	Park, Yoo & Lee (2006)	2.26 (0.47)	7.18						
	Tasy et al. (2008)	0.81 (0.27)	22.13						
			100%						
Lay People	An (2006)	2.10 (0.39)	37.82						
	Lee 1 (2008)	1.59 (0.38)	39.10	1.81	1.34 2.28	7.57	0.91	0	25
	Lee 2 (2008)	1.71 (0.50)	23.08			(<.001)	(.633)		
			100%						

Fatigue



Sleep



Pain

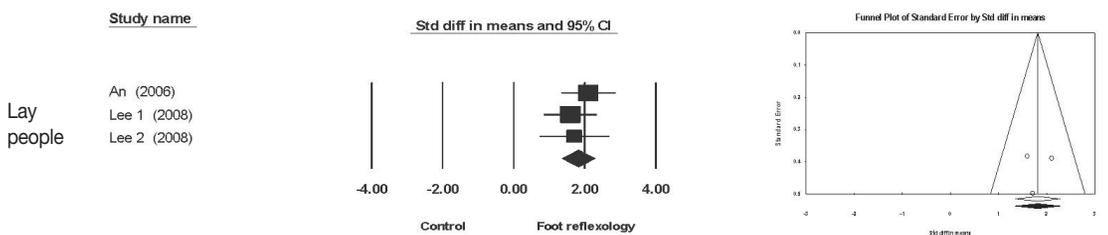
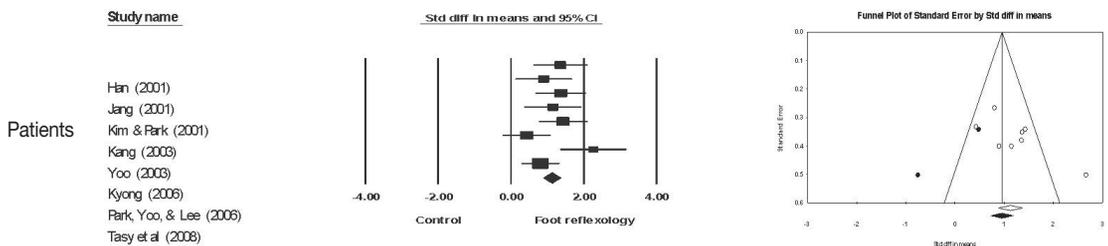


Figure 2. Forest plot & funnel plot for patients and lay people: Fatigue, sleep & pain.

utes (long) or less than 30 minutes by their duration. Of the 7 studies in short category, 2 were on fatigue and 2 were on sleep. Therefore, no further analyses were carried out on fatigue and sleep. There were 7 studies on pain in the long category, and 4 studies in the short category. The average effect size of studies in the long category was 1.47 (CI = 1.19, 1.76) but was only 1.00 (CI = 0.66, 1.34) for studies in the short category.

Hoping to suggest a foot reflexology model regarding the duration and frequency, we further scrutinized the study results. The duration and frequencies of the foot massages were diverse. The durations of massages ranged from 1 day to 6 weeks and the number ranged from 1 to 12 massages. Examining the two studies that did not exhibit a significant intervention effect, no consensus was found in terms of duration and frequency – one had 2 massages in 2 days, and the other had 10 massages in 3 weeks. There was no text book, peer reviewed article, thesis or dissertation that gives suggestion about the duration and frequency of foot massage. Therefore, no further analyses were carried out on these's studies.

DISCUSSION

The combined effect sizes and their 95% confidence intervals are presented in this systematic review and meta-analysis of the effects of foot reflexology on fatigue, sleep, and pain. A fixed-effect model was used whenever applicable to calculate the combined effect size. Possible publication bias was investigated by inspecting the funnel plot and by examination of the fail-safe N, and the studies were further scrutinized to isolate characteristics of the studies that may have affected the effect size of foot reflexology. Study results will be discussed from a meta-analysis aspect and from a foot reflexology aspect.

Out of the 3 meta-analyses on foot reflexology (Kim, 2009; Kim, 2011; Min, 2011) published so far, Kim (2009) was the only comparable study because both Min (2011) and Kim (2011) limited their study subjects to cancer patients. We found discrepancy in the number of studies compared to Kim (2009) possibly because of the stringent inclusion criteria applied in the process of the systematic review.

The effect sizes for each outcome variable were not homogeneous for the following possible reasons: a) foot reflexology interventions varied in terms of time per session (min), duration massages applied (weeks), number of sessions, total time, and subject characteristics; and b) there were studies with very large effect size. Kim (2009) also

reported heterogeneity of the studies. Our analysis was not consistent with Kim (2011), in which the subjects were homogeneous.

According to The Cochrane Collaboration (2002), it is meaningful to estimate the combined effect size even when the effect sizes are heterogeneous. The combined effect sizes from both the fixed effect and random effect models were calculated and compared using the sensitivity analysis (The Cochrane Collaboration, 2002). Because no reference values have been presented for a 'large' difference, we considered a 10% difference to be large, adopting the reference value from the publication bias (Sutton et al., 2000). If the difference between two effect sizes was less than 10%, the results of the fixed effect model were presented. This method was consistent with Kim (2011), who reported fixed effect results when the effect sizes were heterogeneous.

One of the threats to meta-analyses is publication bias. In this study, along with the fail-safe N, a funnel plot was examined, and the trim and fill method was applied to detect possible publication bias (Sutton et al., 2000). If the funnel plot was not symmetric about the combined effect size, then the trim and fill method was applied. If the corrected effect size was more than 10% different from the observed effect size, then publication bias was considered to be possible. Of the three outcome variables considered in this study, the studies on pain seemed to exhibit publication bias. As suggested by Park (2011), rigorous examination of the possible publication biases was performed in our meta-analyses (Park, Kang, Kim, Kim, & Jee, 1998).

Foot reflexology was reported to be effective on fatigue, sleep and pain in all but 2 of the studies reviewed. Both studies were on sleep and had little effects. The effect sizes on fatigue and pain were at least 0.63 and 0.43, respectively. However, the combined effect sizes for fatigue and pain were 'large', and the results were confirmed by a large fail-safe N. The combined effect sizes for sleep, including the 2 studies with little effect, was also 'large' and was confirmed by a large fail-safe N. The combined effect sizes, in order of decreasing magnitude, were fatigue, pain, and sleep. The results were consistent with Kim et al (2006), who reviewed studies about alternative therapy which published during 2000-2004 and concluded that despite variable results, foot reflexology seemed to be effective on treating fatigue, sleep, and pain. The sizes were similar, and the effect of foot-reflexology was consistent with Kim (2009).

In terms of fatigue and sleep, the results were validated because of the use of the fixed effect model and by the lack of publication bias in both cases. In terms of pain, however, we were not as confident in the

results because of the possible presence of publication bias.

Studies were further scrutinized to isolate possible study characteristics that might have resulted in changes in the effect sizes. There were differences in the combined effect sizes between patients and lay people on fatigue and sleep. Foot reflexology was more effective on patients than lay people. This result was consistent with Kim (2009).

Massages typically last for at least 30 minutes because they follow the meridian cycle of 28 minutes (Jeong, 2006). The duration of the sessions varied from 20 minutes to 60 minutes. All of the studies except 2 studies on fatigue and 2 studies on sleep reported massage session durations less than 30 minutes. With only 2 studies, neither homogeneity nor publication bias could be assessed. Furthermore, the effect sizes of the 2 studies on sleep were varied (0.01 and 0.86). Various attempts to detect differences in the study characteristics failed, which led to conclude that foot reflexology was effective regardless of the study characteristics considered. After analyzing 312 studies reporting numerous outcomes of foot reflexology, Kim (2009) reported a larger effect size for the studies lasting 50 minutes per session and longer (14 studies) compared to studies lasting 20 minutes or less (18 studies). Because the effects of foot reflexology were not separately assessed in terms of the outcome variable in the study, no further discussions will be made. However, we recommend that foot massage be applied for at least 30 minutes per session based on the meridian theory.

This study has limitations, which should be considered when interpreting the results. All of the studies adapted a non-RCT design. Because there was no suitable systematic review form for non-RCTs, we had to modify the form for RCT by excluding some of the items that were not appropriate for non-RCTs, such as 'randomization.' The number of studies conducted to evaluate the effects of foot reflexology on fatigue, sleep, and pain were small. Therefore, the results should be interpreted with caution.

CONCLUSIONS

Alternative medicine techniques such as foot reflexology have traditionally been considered to be non-scientific folk remedies used only by less educated and lower class elderly people (Shin & Kim, 2007). In recent years, because foot reflexology is receiving more attention among patients, lay people and health care personnel, efforts have been made to objectively and scientifically evaluate its effective-

ness. We systematically reviewed such studies and meta-analyzed and concluded that foot reflexology was an effective intervention that could alleviate fatigue and sleep disorders.

We have several suggestions for future studies on foot reflexology. First, studies should be randomized whenever possible, and the homogeneity of the subjects should be secured in the study and comparison groups. Means, standard deviations and the number of subjects should be reported in all studies. Second, every effort should be made to ensure a research atmosphere in which non-significant results can be published. Third, the effects of foot reflexology on outcome variables other than fatigue, sleep and pain need to be further evaluated. Lastly, a review form appropriate for non-RCT needs to be developed for future meta-analyses so that non-RCT studies in nursing can also be systematically reviewed.

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