Effects of Ayurvedic Oil-Dripping Treatment with Sesame Oil vs. with Warm Water on Sleep: A Randomized Single-Blinded Cross-over Pilot Study

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Running head:

Effects of Ayurvedic Shirodhara treatment on sleep

Abstract

Objectives:

Ayurvedic oil-dripping treatment (Shirodhara) is often used for treating sleep problems. However, few properly designed studies have been conducted, and the quantitative effect of Shirodhara is unclear. We aimed to quantitatively evaluate the effect of sesame oil Shirodhara (SOS) against warm water Shirodhara (WWS) on improving sleep quality and quality of life (QOL) among those who complain of sleep problems.

Methods:

We employed a randomized, single-blinded, cross-over design and recruited 20 participants. In this cross-over study, each participant received seven sessions of 30 minutes each within 2 weeks, using either liquid. The washout period was set to at least 2 months. The Shirodhara procedure was conducted by a robotic oil-drip system. The outcomes were assessed by the Pittsburgh Sleep Quality Index (PSQI) for sleep quality, Epworth Sleepiness Scale (ESS) for daytime sleepiness, World Health Organization Quality of Life 26 (WHO-QOL26) for QOL, and a sleep monitor instrument for objective sleep measure. Changes between baseline and follow-up periods were compared between the two types of Shirodhara. Analysis was performed with generalized estimating equations.

Results:

Out of 20 participants, 15 completed the study. SOS improved sleep quality, as measured by PSQI. The SOS score was 1.83 points lower (95% confidence interval [CI]: -3.37, -0.30) at 2-week follow-up and 1.73 points lower (95% CI: -3.84, 0.38) than WWS at 6-week follow-up. Although marginally significant, SOS also improved QOL by 0.22 points at 2-week follow-up and 0.19 points at 6-week follow-up compared with WWS. No beneficial effects were observed after SOS on daytime sleepiness or

objective sleep measure.

Conclusions:

This pilot study demonstrated that SOS may be a safe potential treatment to improving sleep quality and QOL in those who have sleep problems.

Introduction

The importance of adequate sleep is globally recognized. However, inadequate sleep and sleep disturbance are widespread problems that aggravate the risk of various lifestyle related diseases and interfere with working capacity and concentration.[1] It is estimated that 4% of American and 5% of Japanese adults take prescription sleep medications, and this number is consistently increasing.[2,3] There is concern among patients about addiction, abuse, and adverse effects of sleep medications.[3] Therefore, expectations are rising toward traditional medicine (TM) and complementary and alternative medicines (CAM) for treating sleep problems. They are considered to be safe and could be substituted for conventional sleep medicines.[4]

The popularity of TM and CAM is increasing in recent years, especially in developed countries.[5-7] Recent studies indicate that a substantial number of people use CAM therapies in their lifetime with the expectation of maintaining and promoting health and curing diseases.[8-10] Ayurveda is one of the most ancient medicines of the world that originated in the Indian subcontinent.[11] It is recognized as a TM by the World Health Organization, and is gaining global acceptance.[12]

In Ayurveda, sleep is considered one of the three supportive pillars to maintain life, along with diet and celibacy (i.e. regulated sexual conduct).[13] Classical textbooks of Ayurveda describe the importance of sleep and various treatments to improve sleep.[14,15] One of the treatments for insomnia in Ayurveda is Shirodhara,[16] an oil-dripping treatment. In Shirodhara, a prescribed liquid (e.g., medicated oil or decoction) is continuously poured over the forehead at a specific temperature and speed for a certain period of time.

Several studies have been conducted to evaluate the effect of Shirodhara on sleep.[17-25] However, properly randomized studies that use standard indices for

evaluation of sleep outcomes are limited. Therefore, the quantitative effect of Shirodhara is still unclear.

We conducted this pilot intervention study in Okayama, Japan, to quantitatively evaluate the effect of sesame oil Shirodhara (SOS) against warm water Shirodhara (WWS) on improvements in sleep quality and quality of life (QOL) among those who complain of sleep problems.

Methods

Study design and participants

We employed a randomized, single-blinded, cross-over design to examine the effect of Shirodhara on sleep. We recruited 22 adult study participants who were complaining of subjective poor sleep quality in the past month (e.g., difficulty in falling asleep or interrupted sleep). Recruitment was completed by distributing a pamphlet to each department of Okayama University and by placing an announcement on the homepage of our office. Those who were taking any treatment for sleep or with any underlying disease like diabetes or hypertension at the time of recruitment were excluded.

The randomization of the participants was performed by block randomization with two participants per block,[26] using a random number table.[27] Participants were allocated randomly to either Group A or B. Because this was a cross-over study, each participant received two different procedures in the first and second terms with a washout period in between of at least two months. Group A received SOS in Term 1 and WWS in Term 2, and Group B received WWS in Term 1 and SOS in Term 2 (Figure 1).

Procedures were conducted from April to August 2013 in Term 1 and from September to December 2013 in Term 2 at a study office in the Department of Human

Ecology, Okayama University Graduate School of Environmental and Life Science.

The participants were informed and fully prepared for the study procedure at an explanatory session before intervention. All participants gave written informed consent.

Demographic questionnaire

A general demographic questionnaire was completed by each participant at baseline (Figure 2). The questionnaire included birthdate; sex; occupation; marital, smoking, alcohol, and exercise status; and medical history.

Shirodhara procedures

Seven sessions of Shirodhara per participant were conducted within 2 weeks during each term. All procedures were conducted by a therapist who was an Ayurvedic doctor certified by the Indian Government and were performed with a robotic oil-drip system called Shirodhara Robot (EM-Techno Co., Ltd., Toyama, Japan). This system automatically pours the liquid over the forehead of the subject with a specified temperature and flow rate (Figure 3).

The liquid used for SOS was unroasted plain sesame oil (Kadoya Sesame Mills Inc., Tokyo, Japan) and that for WWS was plain tap water. Although medicated oils are commonly used for Shirodhara, plain sesame oil was selected in this study because it is considered to be effective and safe and is also often used for Shirodhara in Japan and India. In previous studies, prescribed liquids that were meant for subsiding Vata (one of the biological energies in Ayurveda) were used as Shirodhara liquids. In Ayurveda, the vitiation of Vata is considered to be one of the causes of sleep disturbance.[28,29] According to classical textbooks, sesame oil also has properties to subside vitiated Vata,[30-32] and applying sesame oil on the head produces sound sleep and happiness.[33] A

prior patch test of sesame oil was performed on all participants to assess allergic reactions.

Each procedure was conducted for 30 minutes. The liquid temperature was set at 38.0 ± 0.5°C (April–October) or 39.0 ± 0.5°C (November–December) and the flow rate was fixed at 1.5 L/min. The nozzle from which the liquid came out was set to move side-to-side over the forehead at 10.0 mm/s. The procedure room was maintained at a temperature of 25 ± 1°C with quiet and dim surroundings.

Participants received Shirodhara in the supine position, with the eyes covered with cotton pads and gauze. The body below the neck was covered with a towel. Participants with long hair had their hair bound at the top of his/her head with a hair band. After the procedure the therapist toweled the participant's hair gently, then the participant was asked to rise.

Sleep quality and QOL indices

Three questionnaires were used as primary outcomes to assess treatment effects on sleep quality and QOL. Participants answered these questionnaires three times in each term: 1 week prior to the first session, at 2-week and 6-week follow-up after the intervention period (Figure 2).

Pittsburgh Sleep Quality Index (PSQI). PSQI is a self-rating scale to measure sleep quality and disturbances over a 1-month interval. Higher scores indicate worse sleep quality.[34,35]

Epworth Sleepiness Scale (ESS). ESS is a self-report instrument to measure perception of sleepiness. Higher scores indicate stronger subjective daytime

sleepiness.[36]

World Health Organization-Quality of Life-26 (WHO-QOL26). WHO-QOL26 is a self-reported measure to assess QOL. Higher scores indicate higher QOL.[37]

Sleep monitor measures

As an objective measure for sleep status, we used a mat sleep monitor, Sleepscan SL-503 (TANITA Corporation, Tokyo, Japan), which was placed under the mattress while sleeping. The monitor measures sleep status by respiration, pulse, and body motion, and provides information on Time in Bed (TIB, starting from the moment of intention to fall asleep and concluding with the final arising), Total Sleep Time (TST, actual time slept), Sleep Onset Latency (SOL, how many minutes it takes to fall asleep, starting from the moment of intention to fall asleep), Sleep Efficiency (SE, percent of time in bed spent asleep, calculated as TST/TIB × 100), and Wake After Sleep Onset (WASO, total amount of time awake during the night),[34] etc. This measurement was performed by participants at home every night starting 1 week prior to the first session until 1 week after the 2 week-intervention period (i.e., a total of 28 days). The daily averaged values of the sleep monitor during week 0, weeks 1 and 2, and week 3 were calculated as values of pre-intervention, 2-week intervention, and post-intervention, respectively, and these values were used for analysis (Figure 2). When the participants failed to monitor and the data were missing, we calculated the average values with the data from remaining days.

Statistical Analysis

All outcome measures (i.e., PSQI, ESS, WHO-QOL26, and sleep monitor

measures) were treated as continuous variables. Before assessing the effects of SOS, the pre-test to check the assumption of negligible carryover effects[38] was done for outcomes, as is routine for cross-over studies. To assess the effects of SOS, we used linear generalized estimating equations (GEE),[39] taking into account of within-individual correlation in the cross-over study design. In the analysis, the effects of SOS on all outcomes during the follow-up periods were estimated compared with WWS, considering the baseline differences between the two groups. We assumed within-individual exchangeable correlation and did not adjust for covariates considering the design (i.e., randomized cross-over design).

For primary outcomes (i.e., PSQI, ESS and WHO-QOL26), we first estimated the effects of SOS from baseline to 2-week follow-up (model 1) and then from baseline to 6-week follow-up (model 2) (Figure 2). For sleep monitor measures, we first estimated the effects of SOS on changes in average values between week 0 (pre-intervention) and weeks 1 and 2 (2-week intervention) (model 1), and then between week 0 and week 3 (post-intervention) (model 2).

All confidence intervals (CIs) were calculated at the 95% level. All analyses were performed using Stata statistical software (Stata SE version 12.1, Stata Corp LP, TX, USA). Approval for this study was obtained from the Institutional Review Board of Okayama University Graduate School of Medicine, Dentistry, and Pharmaceutical Sciences (No. 652).

Results

Figure 1 shows the participant flow chart. The 22 participants were randomly allocated equally into each group. Two participants allocated to Group A dropped out for personal reasons before the intervention began. Therefore, in Term 1, 9 and 11

participants received SOS and WWS, respectively. All participants completed Term 1, but 1 participant in each group refused to measure the sleep monitor and 1 participant in Group B did not return the 6-week follow-up questionnaires. Four participants withdrew from Group B during the study before Term 2, and 1 participant from group B dropped out during Term 2. Therefore, 20 participants (Group A: n = 9, Group B: n = 11) in Term 1 and 15 participants (Group A: n = 9, Group B: n = 6) in Term 2 were included in the analysis.

Baseline characteristics of the participants are shown in Table 1. The proportion of female participants was 75.0% (n = 15) and mean age of all participants was 42.0 ± (standard deviation: 7.2) years old. No substantial baseline differences existed between the two groups and these were well matched for possible known confounders (e.g., age, sex, smoking status, alcohol consumption, and exercise).

Table 2 shows the results from GEE analysis on the effect of SOS compared with WWS on primary outcomes. SOS reduced the PSQI score by 1.83 (95% confidential interval [CI]: -3.37, -0.30) and 1.73 (95% CI: -3.84, 0.38) compared with WWS (i.e., improved sleep quality) from baseline to 2-week follow-up and to 6-week follow-up, respectively. Although marginally significant, SOS also improved QOL by 0.22 points at 2-week follow-up and 0.19 points at 6-week follow-up compared with WWS. However, we did not observe any beneficial effect of SOS on ESS.

The results on sleep monitor measures are shown in Table 3. We did not observe any beneficial effects of SOS on changes in average values between pre-intervention and 2-week intervention and post-intervention.

Although there was no serious adverse event during procedure periods, five minor events were reported by four participants. One participant complained of slight pain in the right knee and cold-like symptoms in Term 1 while taking WWS. Although

this participant completed only four sessions out of seven in Term 1, we included this participant in the analysis. Another three participants complained of cold-like symptoms during Term 2, one of which was taking WWS and the others taking SOS. One of them taking SOS discontinued participation after taking 1 session and was excluded from the analysis of Term 2 as shown in Figure 1. The other two participants re-scheduled and restarted the sessions after recovery.

Discussion

In this pilot study, we evaluated the effect of sesame oil Shirodhara (SOS) on sleep quality and QOL compared with warm water Shirodhara (WWS) for those who were complaining of sleep problems. We observed that SOS improved sleep quality and QOL, but not subjective daytime sleepiness or sleep monitor measures.

SOS improved subjective sleep quality measured by Pittsburgh Sleep Quality Index (PSQI), in particular from baseline to 2-week follow-up. This result is consistent with previous studies that demonstrated the effect of Shirodhara on improvement of subjective sleep quality.[17-25] However, those studies assessed sleep quality with different indices, most of which are neither standardized nor validated, and are difficult to compare with this study. Furthermore, they showed the results merely by p-value, which did not give any quantitative information. In contrast, this study used standardized indices for assessing sleep quality, and showed quantitative point estimates with interval estimates considering baseline differences by using GEE analyses. In that respect, our study provides the additional evidence. In addition, our results indicate that the effect of SOS on sleep quality trended in a positive direction at 6 weeks after intervention. SOS may have the long-term effects on sleep quality. Because the minimal clinically important difference for PSQI is sometimes set at an improved score of 3, [40] the

difference of 1.83 (in short-term) or 1.73 (in long-term) in total (Table 2) may not be large enough to generate clinical significance. Although the result did not reach the statistical significance at 5% level due to small number of cases, 27% of the SOS group achieved the improved score of 3 for PSQI from baseline to 2-week follow-up compared with 5% of the WWS group (data not shown), which may show some potentials for clinical significance of the intervention.

For the Epworth Sleepiness Scale (ESS), the beneficial effect of SOS was not observed. Previous studies[17-25] did not use this scale aside from one study[17] for assessing daytime sleepiness. Instead they used subjective experiences such as yawning, drowsiness, fatigue and lack of concentration, and they just compared subjective symptoms from before to after treatment. There was a trend of subjective improvement on those symptoms. One study[17] mentioned the use of ESS in its “materials and methods” section, but the result was not described in the “results” section. Therefore, it is difficult to compare the results of this study with previous studies. One possible reason that SOS did not show beneficial effects in the present study is that seven sessions may have not been enough to produce significant changes in daytime sleepiness. Most other studies set the number of interventions to more than seven sessions.

Although the effect was marginally significant, the result of WHO-QOL26 indicated that SOS improved QOL during both periods. Improvement in sleep quality might be related to better QOL. No previous studies measured QOL changes, and the result cannot be compared.

We did not observe beneficial effects of SOS from the results of the sleep monitor. This may be because the validity of the instrument has not been verified. Moreover, some participants might have difficulty following instructions (e.g.,

forgetting to turn on the instrument before sleep). Assessing objective sleep quality using valid objective instruments in future studies is necessary.

Our result of PSQI would be supported by the findings of the previous studies that demonstrate Shirodhara is associated with decreased sympathetic nervous system tone and increased skin temperature of the hand and foot.[41,42] When the sympathetic nervous system relaxes, peripheral blood circulation and skin temperature will increase.[43] This situation might induce shorter sleep latency and better sleep quality.[42,44-46] However, the long-term duration of this mechanism is unknown.

To our knowledge, this is the first study that evaluated the effect of SOS on sleep quality and QOL compared with that of WWS in a randomized and single-blinded design. The cross-over design adopted in this study eliminates between-patient variation and requires lower sample sizes than those in parallel-group trials to obtain the same number of observations.[38,47,48] Moreover, we used a robotic Shirodhara system which eliminates variability of between and within therapists and maintains stable procedures with fixed flow and temperature of the liquid in each session.

There are some limitations in our study. First, since this was a pilot and exploratory study, the number of participants was relatively small. Moreover, 25% of the total participants (n = 5) did not complete the study. Second, as a pilot study, the number of sessions was relatively small, and might have been too few to generate beneficial changes in results. Most of the Shirodhara studies conducted in India usually set 21 sessions per participant, and Shirodhara treatment may need to be performed for longer periods to expect therapeutic effects. Practically various medicated oil, decoction or other liquids are used for Shirodhara depending on the purpose of treatment in India.[16] On the other hand, plain sesame oil instead of medicated oil is usually used in Japan due to availability and pharmaceutical regulations. We thus used plain sesame oil

in this study. If medicated oil had been used, the results would have likely been more favorable. Ideally, the time length of the procedure is to be decided depending on nature of the illness and the condition of the client and it ranges from 30 to 90 minutes.[16] In this study, we fixed the length of time at 30 minutes for all participants. Again, the result would have been different if we had customized the time length of procedure for each participant. The rate of the dripping and amount of liquid in this study were as per the specification of Shirodhara Robot, and they were similar to ordinal Shirodhara setting. Third, in this study, the control intervention was set as WWS, so both the Shirodhara treatments share common conditions except the liquid properties, which weakens any the differences in outcomes between these two methods. Fourth, the blinding to the participants may not have been perfectly maintained. According to the post-study questionnaire, some participants correctly guessed which liquid was used for each treatment. If they noticed that SOS was the targeted treatment of this study and WWS was the control, it might have influenced their questionnaire scores that strengthened the results. Fifth, some participants took sessions during hot and cold seasons, i.e., July–August and December, respectively. These climatic alterations probably affected sleep, which could be reflected in their questionnaire scores. Finally, the inclusion criteria were developed according to subjective complaints of sleep problems, and were not assessed or diagnosed by standard measures. Of four participants, the scores of PSQI were less than 5 at baseline in Term 1, which suggested that they did not have sleep problems. If we had restricted the inclusion criteria to those who actually had sleep problems at the time of recruitment, then the effects would have been more apparent.

Conclusions

This pilot study demonstrated that SOS may be a safe potential treatment to

improve sleep quality and QOL for those who have sleep problems.

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Disclosure Statement

No competing financial interests exist.

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Fig. 1.

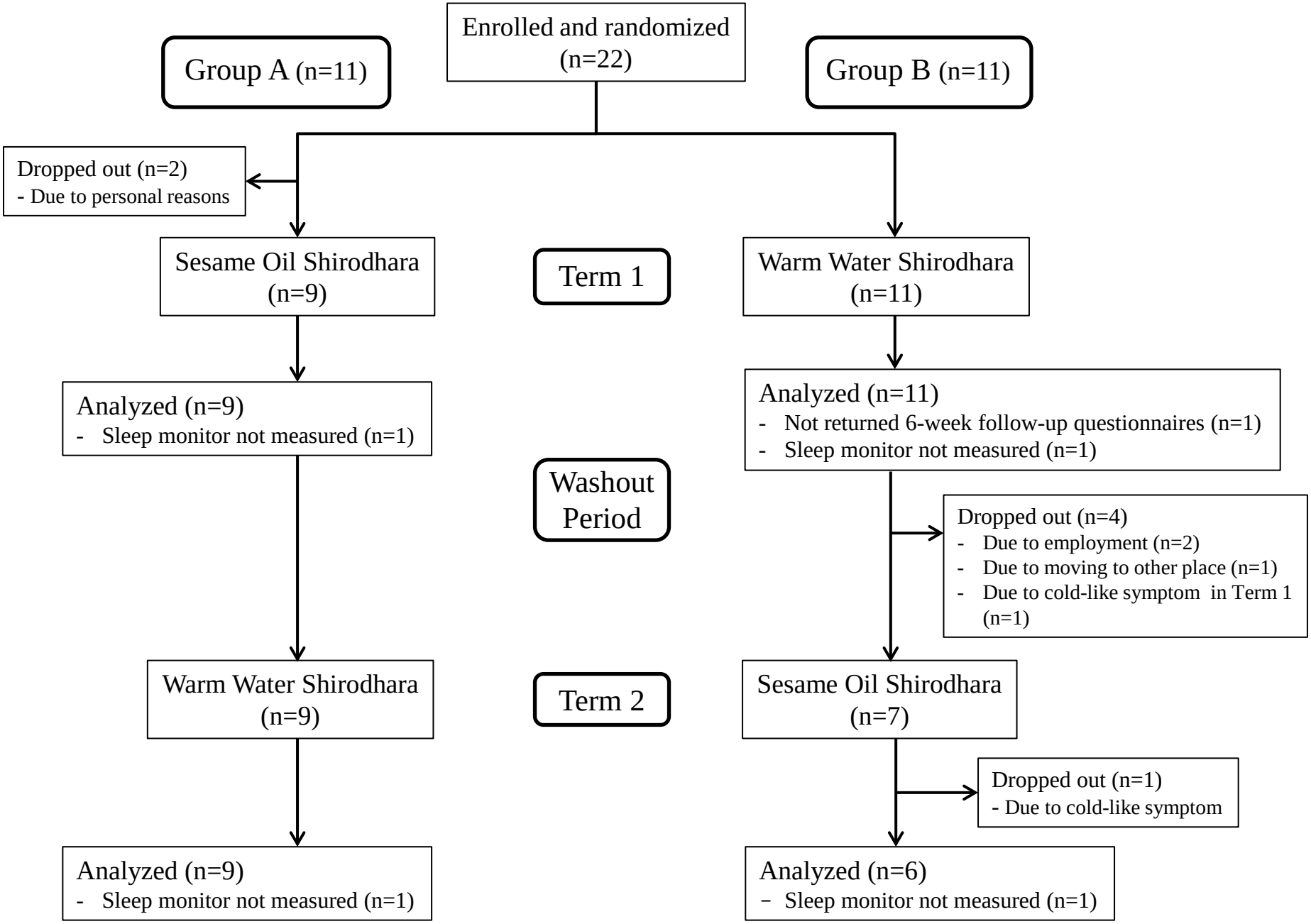
Flow chart of the 22 participants throughout the trial.

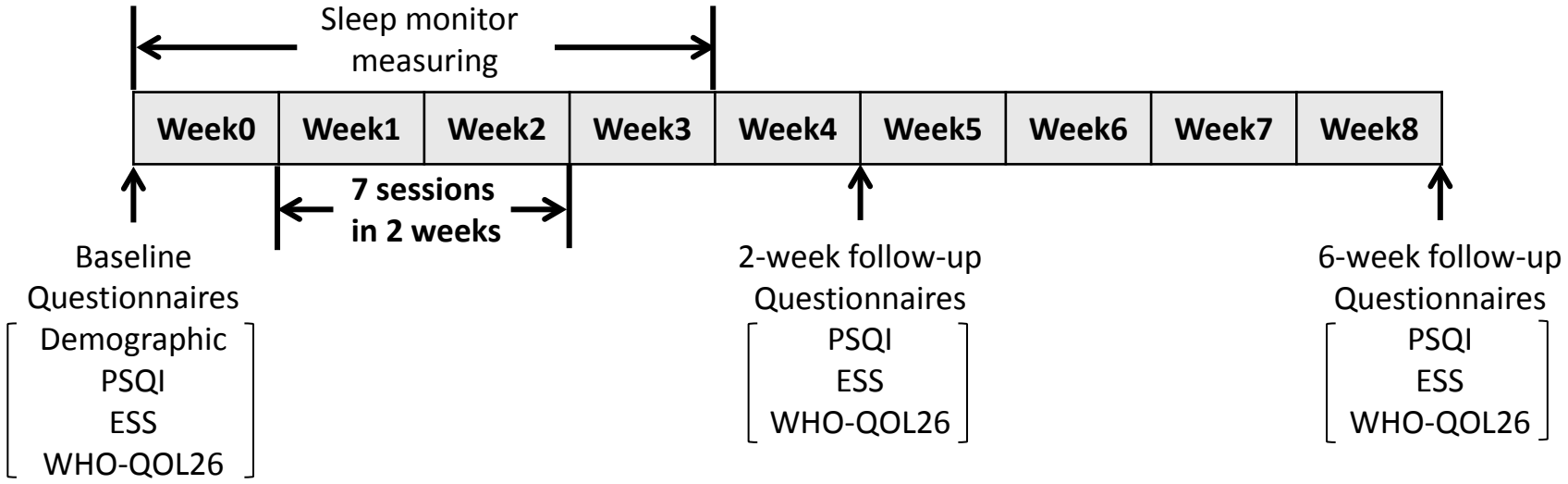
Fig. 2.

Schedule of outcomes measures in each term. Questionnaires include general demographic questionnaire, PSQI (Pittsburgh Sleep Quality Index), ESS (Epworth Sleepiness Scale), and WHO-QOL26 (World Health Organization Quality of Life-26). The general demographic questionnaire was asked only at baseline in Term 1. Sleep quality was measured with a Sleepscan SL-503.

Fig. 3.

Shirodhara robotic oil-drip system. The liquid was warmed and circulated inside the system and poured on the forehead of the receiver through a bundle of cotton strings attached under the nozzle. The ends of the strings were set 8 cm above the forehead. Temperature, pattern, and flow speed can be specified.


Enrolled and randomized (n=22)
Group A (n=11)
Group B (n=11)
Dropped out (n=2)
- Due to personal reasons
Sesame Oil Shirodhara (n=9)
Term 1
Warm Water Shirodhara (n=11)
Analyzed (n=9)
- Sleep monitor not measured (n=1)
Analyzed (n=11)
- Not returned 6-week follow-up questionnaires (n=1)
- Sleep monitor not measured (n=1)
Washout Period
Dropped out (n=4)
- Due to employment (n=2)
- Due to moving to other place (n=1)
- Due to cold-like symptom in Term 1 (n=1)
Warm Water Shirodhara (n=9)
Term 2
Sesame Oil Shirodhara (n=7)
Dropped out (n=1)
- Due to cold-like symptom
Analyzed (n=9)
- Sleep monitor not measured (n=1)
Analyzed (n=6)
- Sleep monitor not measured (n=1)



PSQI, Pittsburgh Sleep Quality Index; ESS, Epworth Sleepiness Scale; WHO-QOL26, World Health Organization - Quality of Life 26

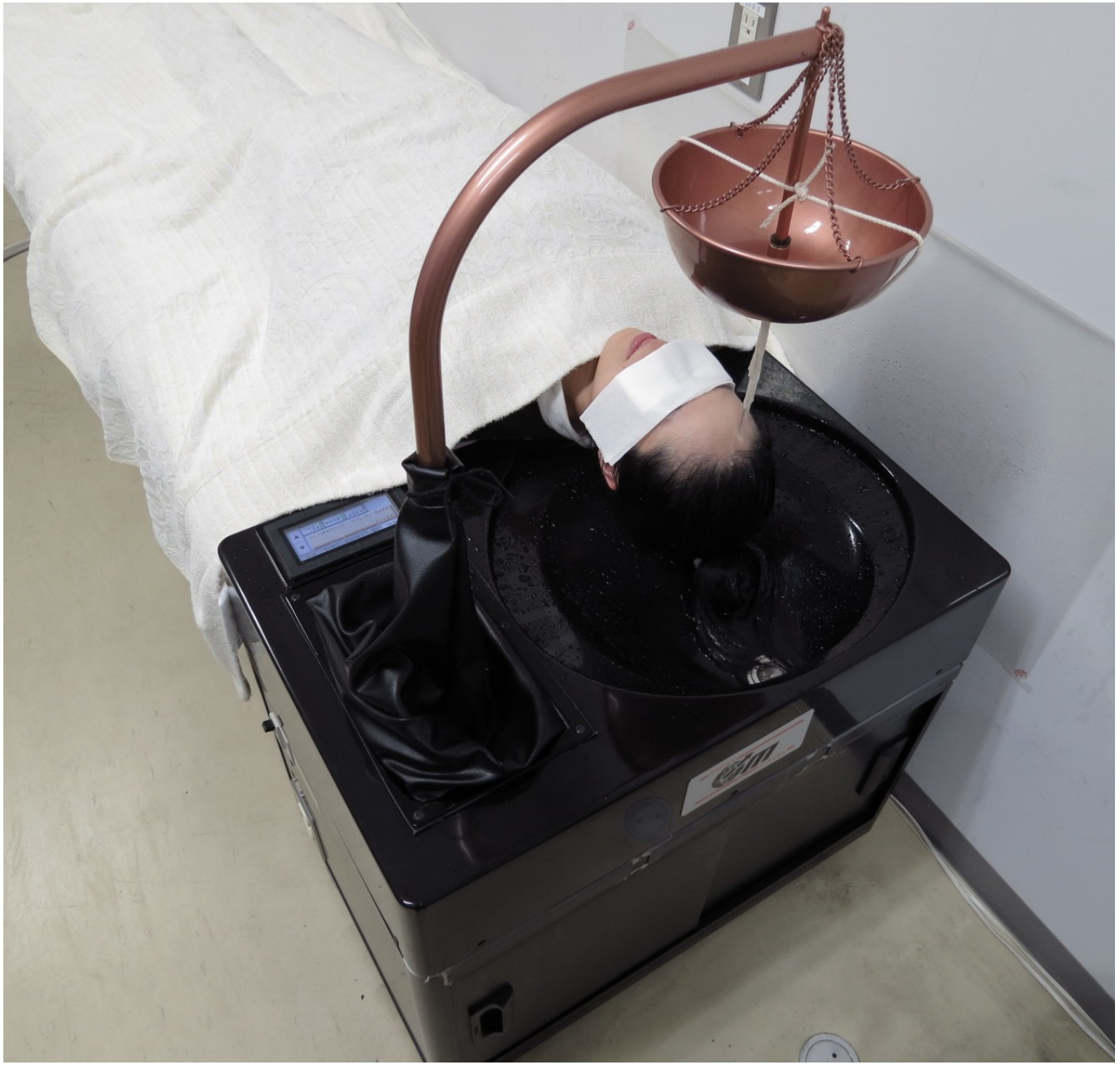


Table 1. Participant characteristics

	Group A (n=9)		Group B (n=11)		Total	
Sex						
Female, n (%)	7	(77.8)	8	(72.7)	15	(75.0)
Male, n (%)	2	(22.2)	3	(27.3)	5	(25.0)
Age (mean, SD)	40.6±7.4		43.1±7.2		42.0±7.2	
Smoking behavior, n (%)						
Never-smoker	6	(66.7)	9	(81.8)	15	(75.0)
Current-smoker	2	(22.2)	1	(9.1)	3	(15.0)
Ex-smoker	1	(11.1)	1	(9.1)	2	(10.0)
Alcohol consumption, n (%)						
No / Rarely	5	(55.6)	7	(63.6)	12	(60.0)
≥1 time per week	4	(44.4)	4	(36.4)	8	(40.0)
Exercise, n (%)						
No	3	(33.3)	4	(36.4)	7	(35.0)
≥1 time per week	6	(66.7)	7	(63.6)	13	(65.0)
Baseline PSQI score (mean, SD)	7.1±2.3		5.8±1.9		6.4±2.1	
Baseline ESS score (mean, SD)	12.3±3.4		10.0±2.9		11.1±3.3	
Baseline QOL score (mean, SD)	3.1±0.3		3.3±0.4		3.2±0.4	

SD, standard deviation; PSQI, Pittsburgh Sleep Quality Index; ESS, Epworth Sleepiness Scale;

QOL, World Health Organization Quality of Life 26

Table 2. GEE analysis of the effects of Sesame Oil Shirodhara comparing with Warm Water Shirodhara on sleep quality and quality of life between baseline and two follow-up periods

Outcome	Model 1 (Between baseline and 2-week follow-up)				Model 2 (Between baseline and 6-week follow-up)		
	Effect of SOS	95% CI			Effect of SOS	95% CI	
		Lower	Upper			Lower	Upper
PSQI	-1.83	-3.37	-0.30	*	-1.73	-3.84	0.38
ESS	-0.75	-3.38	1.88		1.31	-0.75	3.36
QOL	0.22	-0.02	0.46		0.19	-0.07	0.45

GEE, Generalized Estimating Equations; SOS, sesame oil Shirodhara; PSQI, Pittsburgh Sleep Quality Index;

ESS, Epworth Sleepiness Scale; QOL, World Health Organization Quality of Life 26;

95% CI, 95% confidence interval

* p-value < 0.05

Table 3. GEE analysis of the effects of Sesame Oil Shirodhara comparing with Warm Water Shirodhara as measured by the sleep monitor on changes in average values before intervention, 2 weeks of intervention, and after intervention

Outcome	Model 1 (Between pre-intervention and 2-week intervention)			Model 2 (Between pre-intervention and post-intervention)		
	Effect of SOS	95% CI		Effect of SOS	95% CI	
		Lower	Upper		Lower	Upper
Total Time in Bed (TIB), min	8.4	-27.2	44.0	-22.4	-61.4	16.6
Total Sleep Time (TST), min	8.8	-27.6	45.2	-25.9	-60.5	8.7
Sleep Onset Latency (SOL), min	3.6	-4.6	11.8	4.9	-5.3	15.2
Sleep Efficiency (SE), %	1.8	-1.6	5.2	0.6	-2.6	3.8
Wake After Sleep Onset (WASO), min	-4.4	-13.1	4.3	-1.9	-11.0	7.3

GEE, Generalized Estimating Equations; SOS, sesame oil Shirodhara; 95%CI, 95% confidence interval