Effect of Inhaled Lavender and Sleep Hygiene on Self-Reported Sleep Issues: A Randomized Controlled Trial

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Abstract

Objectives: To compare the effectiveness of lavender (*Lavandula angustifolia*) and sleep hygiene versus sleep hygiene alone on sleep quantity and sleep quality and to determine sustained effect at two-week follow-up. *Design:* A randomized controlled trial with investigator blinding and steps taken to blind the participants. *Setting:* Participants' usual sleep setting.

Subjects: Seventy-nine college students with self-reported sleep issues.

Interventions: The intervention took place over five nights with baseline, postintervention, and two-week follow-up assessments. Both groups practiced good sleep hygiene and wore an inhalation patch on their chest at night. One group wore a patch with 55 μ l of lavender essential oil and the other group wore a blank patch. *Outcome measures:* Sleep quantity was measured using a Fitbit[®] tracker and a sleep diary, and sleep quality

was measured using the Pittsburgh Sleep Quality Index (PSQI) and the NIH Patient-Reported Outcomes Measurement Information System (PROMIS) sleep disturbance short form.

Results: The lavender and sleep hygiene group demonstrated better sleep quality at postintervention and twoweek follow-up (PSQI p=0.01, <0.001 and PROMIS p=0.04, 0.007, respectively). The sleep-hygiene-only group also demonstrated better sleep quality but to a lesser extent (PSQI p=0.02, 0.06 and PROMIS p=0.03, 0.03, respectively). Additionally, a clinical effect was found for the lavender group at postintervention, along with a significant finding for waking feeling refreshed (p=0.01). Sleep quantity did not differ between groups. **Conclusions:** Lavender and sleep hygiene together, and sleep hygiene alone to a lesser degree, improved sleep quality for college students with self-reported sleep issues, with an effect remaining at follow-up.

Introduction

S LEEP ISSUES ARE PREVALENT in our 24/7, nonstop society, with 25–65% of children, adolescents, and adults having sleep issues, depending on the definition of sleep issues or insomnia.^{1–3} Difficulty with sleep initiation, sleep maintenance, or daytime sleepiness can affect health, safety, and performance. Health effects associated with sleep problems include decreased well-being, fatigue, anxiety, depression, cardiovascular disease, hypertension, inflammation, obesity, diabetes, and impaired glucose tolerance.⁴ Costs of sleep issues are in the tens of billions of dollars annually.^{5–9} Identification of effective self-care sleep interventions is needed and primary care providers can play a key role in recommending self-care sleep interventions as first-line treatments for their patients with sleep issues.

Mild insomnia is frequently self-treated using over-thecounter medications, herbs, or strategies such as sleep hygiene, cognitive behavioral therapy, and sleep restriction therapy that modify its precipitating and contributory factors.¹⁰ More severe insomnia is treated with hypnotic drugs that are considered safe for short-term use, but are often prescribed long-term and have many side effects.^{11–16} Despite the use of a variety of treatments, short-term insomnia frequently becomes chronic insomnia.¹⁷ Additionally, many people do not treat their insomnia.¹ Both ineffective treatment and lack of treatment contribute to the development of chronic insomnia and the prevalence of sleep issues.

Cost-effective, convenient, accessible, and safe interventions for addressing sleep issues can aid in decreasing the associated wide ranging health effects of lack of sleep. Essential oils with sedative or hypnotic properties are promising as a sleep therapy. Inhaled, their chemical constituents enter the circulatory system through the lungs and the neurochemical pathway via the limbic system.¹⁸ A systematic review of the literature on inhaled essential oils and sleep¹⁹ and

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2 additional studies^{20,21} identified 17 studies with a wide variety of methodologies. Thirteen of the studies were randomized controlled trials (RCTs).^{20–32} Lavender essential oil was most frequently studied, with results trending toward a positive effect.^{20,21,23–26,28–31,33–36} A small to moderate benefit of lavender on sleep was found in a systematic review of the literature specific to lavender and sleep.³⁷

Lavender (*Lavandula angustifolia*) essential oil was selected for the study intervention based on its documented sedative and hypnotic properties¹⁸ and its safety profile.³⁸ College students were selected as the population of the study because early intervention in young adults can offer prevention for chronic insomnia as they become older adults. Sleep hygiene instruction, a cognitive/educational intervention, was included as usual care.

The objective of this study was to investigate the effect of inhaled lavender (*L. angustifolia*) and sleep hygiene on sleep quality and quantity compared to sleep hygiene alone in college students with self-reported sleep issues and to determine if any effect is sustained at two-week follow-up.

Materials and Methods

Participants and setting

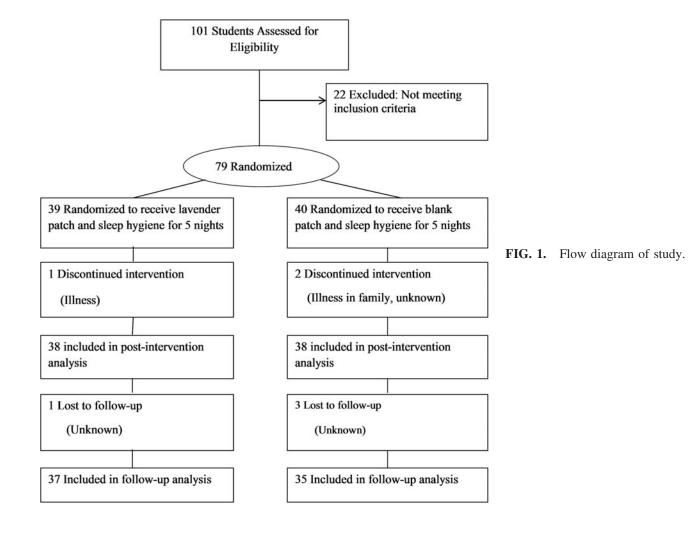
Participants were recruited (fall 2013) using flyers posted around campus and presentations of the study to health advocates in on-campus living facilities. Inclusion criteria were as follows: English-speaking college student, ≥ 18 years old with self-reported sleep issues (difficulty falling asleep, frequent awakenings during the night, or daytime sleepiness), and able to attend two study visits at the health center. Exclusion criteria were pregnancy, night shift work, or use of prescription sleep medications. Of the 101 individuals who completed the screening for eligibility assessment, 22 individuals were excluded (Fig. 1). The setting was the participants usual sleep setting.

Study design

This was a parallel-group RCT with participant and investigator blinding. Participants were randomized into one of two groups upon enrollment using a 1:1 allocation ratio. Simple randomization was completed by a noninvestigator and envelopes were used to maintain blinding. Group 1 (LSH) was assigned to use lavender patches plus sleep hygiene (n=39) and group 2 (SH) was assigned to use blank patches and sleep hygiene (n=40) for five consecutive nights. Assessments were conducted at baseline, during the intervention, postintervention, and at two-week follow-up. The study was approved by the University of Minnesota human subjects committee.

Outcome measures

Outcome variables measured included both sleep quantity and sleep quality to determine the effect of lavender on



each. Participants completed sleep quality surveys (Pittsburgh Sleep Quality Index [PSQI] and the NIH Patient-Reported Outcomes Measurement Information System [PROMIS[™]] sleep disturbance short form 8b) and a sleep hygiene survey (SHS) at baseline, postintervention, and at two-week follow-up. During the intervention Fitbit[®] trackers were to be worn at night and online sleep diaries completed in the morning.

Fitbit One[™] wireless activity tracking device. This device tracks sleep based on movement. It was shown to have an intradevice reliability of 96.5–99, comparable to both polysomnography and actigraphy. Similar to actigraphy, it was found to misidentify wake as sleep compared to polysomnograph.³⁹ Self-report such as a sleep diary has been recommended as a supplement.⁴⁰

Daily sleep diary. This is a standard means to collect quantitative sleep data and was used to supplement the Fitbit One for sleep quantity information and to provide a daily perspective on sleep quality. The sleep diary for this study was an adaptation of the National Sleep Foundation Sleep Diary. It included questions on sleep quality, sleep disturbances, adverse effects, and adherence to use of the tracker and patch.⁴¹ Sleep diaries have been found to be more reliable than actigraphy.⁴²

Pittsburgh Sleep Quality Index. This survey generates seven component scores: sleep quality, sleep latency, sleep duration, sleep efficiency, sleep disturbance, sleeping medications use, and daytime functioning. The sum of these components yields a global score of 21, a higher score indicating poorer sleep quality. A PSQI score greater than five distinguishes poor sleepers and a change in three points suggests a clinical effect. This instrument has been found to have a high test–retest reliability and good validity for use with good and poor sleepers.⁴³ It assesses sleep quality and disturbances for up to a one-month period and has been found to have higher test–retest reliability for shorter intervals.⁴⁴ It is a recommended measure for treatment effectiveness studies for global sleep quality.⁴⁰

NIH Patient-Reported Outcomes Measurement Information System sleep disturbance short form (SF8b, PROMIS v.1.0 www.nihpromis.org). This survey served as an additional sleep quality instrument. This short form correlates strongly with the PROMIS sleep disturbance long form. It was developed for samples with or without sleep disorders and measures sleep quality and disturbance over a previous one-week interval. This instrument has been validated for sleep–wake function but not for responsiveness to change. The total possible score is 40, with a higher score indicating more disturbed sleep.^{45,46}

Sleep Hygiene Questionnaire. This survey was administered to assess compliance with the recommended sleep practices.⁴⁷ Total possible score was 112, with a higher score indicating poorer sleep practices. The instrument was found to have acceptable test–retest reliability, although internal reliability was poor. This may reflect that hygiene practices change over time.⁴⁸

Materials

Patch. The 3 cm adhesive patch contained a 1 cm disc of absorbent material that contained 55 μ l of lavender oil applied consistently by a metered pump for the lavender group and left blank for the placebo group. According to the manufacturer, the patch has a time release function allowing it to last for 6–8 hours. The patch has a skin barrier backing so that essential oils are inhaled but not absorbed standardizing the route of administration (Bioesse Technologies, LLC, Minnetonka, MN).

L. angustifolia essential oil. A gas chromatography/mass spectrometry (GC/MS) chemical analysis for the batch of lavender oil utilized in the study was provided to the PI to ensure treatment integrity. The essential oil used was chemically consistent with the International Organization for Standardization (ISO) for *L. angustifolia*.⁴⁹

Procedure

This study was completed in 4 waves of about 20 students each. The principal investigator (PI) conducted both intake and assessments. Screened and consented respondents were scheduled for initial and postintervention sessions. Roommates who were screened and met inclusion/ exclusion criteria were scheduled for different waves of the study to maintain participant blinding to the degree possible (n=2). Assessments were administered online via the PROMIS Assessment Center.

Participants were provided with six patches, a Fitbit One tracker, and detailed written and verbal instructions for the patch and the tracker. The participants were instructed to adhere the patch to the mid-upper chest and to place the tracker on their nondominant wrist before going to bed and to remove them in the morning. The patches for the two groups were packaged identically except for group code number. A noninvestigator validated code assignments so the investigator remained blinded to treatment. Participants were informed that the groups differed in the dosage of essential oil. The name of the essential oil and the exact dosages were not provided to the participants. Both groups received sleep hygiene information and were asked to practice the guidelines during the intervention. The sleep hygiene recommendations were (1) maintain a regular sleep schedule, (2) avoid fluid intake before bed and food, caffeine, alcohol, and nicotine late in the day, (3) create a good sleeping environment (e.g., wear ear plugs and a sleep mask and avoid screens and texting), (4) create a relaxing bedtime routine, (5) keep up with school work, and (6) exercise regularly. This list is based on the NIH-recommended list of sleep practices,⁵⁰ with some modifications for college students. 51-53

Participants were instructed to begin the intervention on Sunday evening and end it Friday morning. They received email and text reminders in the evening to use the patch and Fitbit device and in the morning to complete the sleep diary. They were instructed to return the Fitbit device and any remaining patches at their postintervention session. For the follow-up assessment, a link was e-mailed to each participant 14 days after intervention completion with a reminder text message if the surveys were not completed within a day and a half.

Statistical analyses

Sample size determination. Sample size determination was based on analysis of covariance for the main outcome, the PSQI, with a 2-tailed alpha of 0.05 and a power of 80%. A clinically significant effect size was set at three based on results of other studies.⁴³ Sample size was determined to be 25 participants in each group using a standard deviation of 4.57.⁴³

Data analyses. Analysis was performed in SAS version 9.2, SPSS 21, and R version 2.15.1. Linear regression was used when there were single observations on an individual for the specified model and data were approximately normal. Generalized estimating equation (GEE), which accounts for the correlation that occurs on repeated measurements of an individual, was utilized for models with multiple observations over time. The most appropriate covariance structure was selected based on the nature of the correlations between the repeated measurement data and the limitations of the software (SAS allows only independent covariance structure for multinomial outcomes). In summary, appropriate models were chosen based on the distribution of the response variable, whether response variables were repeatedly measured, and the covariance structure between repeated measures.

A series of models were created beginning with full models using all parameters and subsequent models that reduced parameters based on their statistical significance in the full models. Parameters that remained in the reduced models regardless of significance were age, gender, sleep hygiene score, treatment group, patch worn, and time for longitudinal models. Results were considered significant at a 2-sided α =0.05. The NIH Assessment Center provides normalized *T*-scores for analysis on the PROMIS sleep disturbance questionnaires. Raw scores were used for analysis in this study because the normalized *T*-scores were calibrated against a sicker population than the general U.S. population, in contrast to the healthy college student sample in this study.⁵⁴

Missing data were handled appropriately for each statistical method. For summary statistics missing data were ignored, and for data in long format (GEE and regression) estimates were generated for every variable based on the data present. Weighted sums and percentages were used to account for missing data on the daily sleep diary.

Results

The overall sample was two-thirds female and one-third male, the mean age was 21.6, and the majority of participants were white and not Hispanic or Latino (Table 1). The two groups were demographically similar, with race the only factor for which there was a statistically significant difference between groups (p = 0.02).

Participants reported use of the patch and the Fitbit each morning on the sleep diary. Although subjects reported wearing the Fitbit 92% of the cumulative person-nights (n=365), data were recoverable for only 14% of the person-nights (n=57). Despite assistance from the manufacturer and additional instruction to the participants, technical issues related to the Fitbit device resulted in unacceptable levels of missing data. Participants (n=369). This number

Characteristic	Lavender patch+sleep hygiene (LSH group) (n=39)	Blank patch+sleep hygiene (SH group) (n=40)	Total (n = 79)	р	
Age, mean (range), years	20.9 (18-28)	22.1 (18–36)	21.6 (18-36)	0.09 ^a	
Gender, n (%)				9.46 ^b	
Female	25 (64)	29 (73)	54 (69)		
Male	14 (36)	10 (25)	24 (30)		
NA	0 (0)	1 (2)	1 (1)		
Race, <i>n</i> (%)				0.02^{c}	
White	24 (62)	29 (73)	53 (67)		
Black or African American	0 (0)	2 (5)	2(3)		
Asian	13 (33)	4 (10)	17 (22)		
American Indian or Alaskan Native	0 (0)	1 (2)	1 (1)		
Other	0 (0)	1 (2)	1 (1)		
NA	2 (5)	3 (8)	5 (6)		
Ethnicity, n (%)				0.34^{c}	
Not Hispanic or Latino	36 (92)	31 (78)	67 (85)		
Hispanic or Latino	1 (3)	3 (7)	4 (5)		
NA	2 (5)	6 (15)	8 (10)		
Health conditions, $d n (\%)$. /	0.18 ^b	
No	34 (87)	29 (73)	63 (80)		
Yes	5 (13)	11 (27)	16 (20)		

TABLE 1. DEMOGRAPHIC AND CLINICAL CHARACTERISTICS OF PARTICIPANTS

^at-test.

^bChi square.

^cFisher's exact test.

^dHealth conditions reported: depression (n=4), allergies (n=3), asthma (n=3), anxiety (n=2), ADHD (n=2), overweight (n=1), hypertension (n=1), epilepsy (n=1), cyclothymia (n=1), and vitamin D deficiency (n=1). Some participants reported more than one condition.

Group	Assessment	Mean SHS score	SD	Minimum SHS score	Maximum SHS score	Ν	p-Value between group differences
LSH group	Pre	42.72	11.54	20	76	39	
	Post	23.16	11.88	4	45	38	
	Follow-up	31.47	11.07	7	57	36	
SH group	Pre	41.53	10.79	22	66	40	
	Post	21.39	11.34	0	54	38	
	Follow-up	32.23	12.53	3	58	35	
Total	Pre	42.11	11.12	20	76	79	0.64
	Post	22.28	11.57	0	54	76	0.51
	Follow-up	31.85	11.73	3	58	71	0.79

TABLE 2. SHS FREOUENCIES AND MEANS: BETTER SLEEP HYGIENE SCORES POSTTREATMENT AND NO DIFFERENCES BETWEEN GROUPS

SHS score range is 0–112, with lower scores indicating better sleep hygiene.

LSH group, lavender plus sleep hygiene group; SH group, sleep-hygiene-only group; SHS, sleep hygiene survey.

was validated by the number of patches returned. Patches were reported to have fallen off during sleep in 37% of the person nights (n = 146); however, this was not a significant covariate in any of the models. Sleep hygiene practice was assessed at baseline, post-

intervention, and follow-up with the SHS (Table 2); the mean

tion, and follow-up (p = 0.64, 0.51, and 0.79, respectively).

Adverse effects

Adverse effects to the intervention were reported on the daily sleep diary. Only four adverse effects of minor skin irritation were reported lasting one night for each report.

Sleep quantity

total scores were 42.7 (range 20-76), 23.2 (range 0-54), and 31.5 (range 3–58), respectively, where lower scores indicating There were no statistically significant differences in sleep better sleep hygiene practices during the intervention than bequantity between groups based on the sleep diary (Table 3). fore or after. There were no statistically significant differences For both groups the number of awakenings decreased between groups for the SHS scores at baseline, postinterven-(p=0.02) and falling asleep easily increased (p=0.001). Little variability was found for sleep efficiency (number of

Model	Variable	Estimate	Std. error	р
Total time in bed	LSH group	- 11.07	12.28	0.37
	SHS score	-0.49	0.56	0.38
	Time (days)	3.90	-2.33	-0.10
	Age (years)	-3.74	1.43	0.009
	Gender (female)	24.08	12.46	0.05
Total time asleep	LSH group	-11.02	12.19	0.37
	SHS score	-0.50	0.55	0.37
	Time	4.01	2.37	0.09
	Gender (female)	23.75	12.30	0.05
	Age	-3.71	1.44	0.01
Model	Variable	Relative risk	95% CI lower/higher	р
Times awakened	LSH group	1.29	0.86/1.93	0.22
	SHS score	1.00	0.99/1.02	0.68
	Time	.92	0.86/0.99	0.02
	Treatment-time interaction	0.87	0.78/0.98	0.02
	Age (years)	0.99	0.94/1.04	0.73
	Gender (female)	1.07	0.74/1.57	0.71
Model	Variable	Odds ratio	95% CI lower/higher	р
Fell asleep easily	LSH group	1.03	0.61/1.73	0.92
	SHS score	0.99	0.97/1.02	0.53
	Time	1.37	1.16/1.62	0.001
	Age (years)	0.99	0.94/1.04	0.76
	Gender (female)	0.88	0.49/1.59	0.67

TABLE 3. SLEEP QUANTITY RESULTS: POSTINTERVENTION

minutes asleep/number of minutes in bed) with a majority of the results falling in the normal range near 100%.

Sleep quality

There was a statistically significant difference between groups for sleep quality, waking feeling refreshed, and daytime fatigue. The LSH group demonstrated improved sleep quality at postintervention compared to the SH group. This effect remained at two-week follow-up. The findings were consistent for both standardized tools, the PSQI (postintervention p=0.01, follow-up $p \le 0.001$) and the PROMIS sleep disturbance tool (postintervention p=0.04, follow-up p=0.007). Those reporting better sleep hygiene practices on the SHS also demonstrated improved sleep quality but to a lesser extent than the LSH group (Table 4). Better sleep hygiene scores were associated with better sleep quality as measured by the PSQI and the PROMIS survey at postintervention (p=0.02 and 0.03, respectively) and by PROMIS at follow-up (p=0.03). The PSQI mean scores did not differ between groups at baseline (p=0.08) and were greater than 5 (LSH=8.2, SH=8.7), indicating poor sleep before the intervention. While both groups had improved sleep quality at postintervention and follow-up, the LSH

Model	Variable	Estimate	Std. error	р
Post-PSQI global score	-PSQI global score LSH group Post-SHS score Age (years) Gender (female)		0.43 0.02 0.05 0.50	0.01 0.02 0.77 0.57
Follow-up PSQI global score	global score LSH group Follow-up SHS score Time Treatment–time interaction Age (years) Gender (female)		$\begin{array}{c} 0.49 \\ 0.02 \\ 0.03 \\ 0.03 \\ 0.05 \\ 0.43 \end{array}$	<0.001 0.06 0.94 0.02 0.39 0.55
Post-PROMIS total score	LSH group Post-SHS score Age (years) Gender (female)	-1.78 0.09 -0.12 0.22	0.83 0.04 0.10 0.96	$0.04 \\ 0.03 \\ 0.24 \\ 0.82$
Follow-up PROMIS total score	LSH group Follow-up SHS score Time Age (years) Gender (female)	-1.47 0.08 0.01 -0.14 0.66	0.54 0.03 0.05 0.09 0.69	0.007 0.03 0.90 0.12 0.34
Model	Variable	Odds ratio	95% CI lower/higher	р
Post-waking refreshed	LSH group Post-SHS score Time Age (years) Gender (female)	1.87 0.99 1.18 1.01 1.32	1.15/3.03 0.97/1.01 1.02/1.37 0.97/1.05 0.71/2.47	0.01 0.32 0.03 0.56 0.38
Post-daytime sleepiness	LSH group Post-SHS score Age (years) Gender (female)	0.63 1.07 0.86 3.22	0.19/2.08 1.01/1.13 0.74/0.99 0.76/13.63	0.45 0.03 0.04 0.11
Follow-up daytime sleepiness			0.45/1.89 1.00/1.07 1.00/1.07 0.83/0.98 1.04/7.51	0.83 0.09 0.09 0.01 0.04
Post-daytime dysfunction	unction LSH group Post-SHS score Age (years) Gender (female)		0.13/0.84 0.96/1.06 0.85/1.09 0.52/4.72	0.02 0.67 0.56 0.43
Follow-up daytime dysfunction LSH group Follow-up SHS score Time Treatment-time interaction Age (years) Gender (female)		$\begin{array}{c} 0.18 \\ 1.03 \\ 0.93 \\ 1.10 \\ 0.98 \\ 0.84 \end{array}$	0.05/0.66 1.00/1.07 0.86/1.00 1.01/1.20 0.89/1.08 0.38/1.82	$\begin{array}{c} 0.009 \\ 0.09 \\ 0.06 \\ 0.03 \\ 0.75 \\ 0.66 \end{array}$

TABLE 4. SLEEP QUALITY RESULTS: POSTINTERVENTION AND FOLLOW-UP

group at postintervention had a mean PSQI score of 4.9, while the SH group had a mean PSQI score of 6.5. This suggests normal sleep on average at postintervention for the LSH group only. The mean change from baseline to postintervention for the LSH group was 3.2, and so the group receiving lavender demonstrated a clinical effect. No clinical effect was demonstrated for the SH group. The LSH group had less daytime fatigue at postintervention and follow-up (p=0.02 and 0.009, respectively) and was more likely to wake feeling refreshed at postintervention (p=0.01).

Discussion

This RCT with participant and investigator blinding examined the effect of inhaled L. angustifolia and sleep hygiene on college students with self-reported sleep issues and found improved sleep quality in the group receiving lavender at postintervention and at two-week follow-up. Better sleep practices were also independently associated with sleep quality but to a lesser degree. The findings were consistent on all assessment tools and with the literature. Due to the variety of methodologies, direct comparison to previous studies cannot be made. Inclusion of follow-up assessment at two weeks added an important new element to the literature. The persistent effect of lavender on sleep quality at two-week follow-up suggests a re-balancing or long-acting effect on the sleep cycle, although the exact mechanism of action is unknown. No difference between groups was found for sleep quantity, although both groups reported falling asleep easily and less awakenings at postintervention. Participants reported high adherence to the study protocol and few side effects. The findings suggest that the use of lavender and sleep hygiene is a safe and effective intervention for sleep in college students with selfreported sleep issues.

The study had several limitations. The impact of the racial difference between groups is unclear. The missing Fitbit data resulted in only one valid measurement of sleep quantity, the sleep diary, confirming the importance of using supporting measures where possible. Newer versions of personnel trackers may be more valid for research. The selfreport nature of the data is a limitation; however, the instruments used are well tested in many populations. Although the patches did not uniformly remain adhered to the skin overnight, this did not prevent inhalation, as supported by the results. The specific amount inhaled cannot be guaranteed using these methods, which were chosen to provide a somewhat standardized dose in the home setting without specialized equipment. Blinding to smells is difficult and this may have been a factor. This study took steps to blind participants and the investigator was blinded.

Methodological strengths of this study contribute to the sleep self-care and clinical intervention literature. Product integrity verification of the lavender essential oil through GC/MS analysis validated treatment integrity. If not done, doubt is cast on the results because commercially available essential oils may be adulterated. Very few and minor adverse effects were reported, mainly related to the adhesive on the patches rather than the lavender essential oil, supporting its safety. The use of the online Assessment Center for standard sleep measurement tools and managing study flow likely contributed to the high participant adherence to protocols, and these can be replicated and refined in future studies. The use of the participants' normal sleep setting increased external validity, and a follow-up assessment provided important information on the duration of the effect of the intervention.

Conclusions

This RCT supports the use of lavender and sleep hygiene as safe, accessible, and effective interventions for selfreported sleep issues in college students. Further research to study their effect on other populations and additional studies exploring the duration of intervention effects are needed. Safe, effective, self-care interventions such as lavender (*L. angustifolia*) and sleep hygiene are viable as a first-line intervention for sleep issues.

Acknowledgments

Financial and material support was provided by funding through the School of Nursing, Wladimir and Paulina Zenkovich Nursing Fellowship, and the Sophia Fund. The Sigma Theta Tau, Zeta Chapter, provided funding for statistical analysis and dissemination. Boynton Health Service, University of Minnesota, provided funding for Fitbit trackers, logistical assistance with recruitment, and space. Wyndmere Naturals, Inc., and Bioesse Technologies, LLC, supplied materials for this study.

Author Disclosure Statement

No competing financial interests exist for any of the authors. None of the sponsors or funders had any involvement in the design or conduct of the study; collection, management, analysis, and interpretation of the data; or preparation, review, or approval of the article.

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