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A Single-Blinded, Randomized Pilot Study Evaluating the Aroma of *Lavandula augustifolia* as a Treatment for Mild Insomnia

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ABSTRACT

Background: Insomnia is the most common of all sleep complaints and is under-researched. The current treatments of choice are conventional hypnotics agents, but these have potential for serious adverse reactions. Uncontrolled and anecdotal evidence suggests that lavender oil is an effective treatment for insomnia, but this has not been formally investigated.

Objectives: The aims of this study were to evaluate the proposed trial methodology and the efficacy of *Lavandula augustifolia* (lavender) on insomnia.

Interventions: Interventions consisted of *Lavandula augustifolia* (treatment) and sweet almond oil as placebo/control. The aroma was supplied via an Aromastream device (Tisserand Aromatherapy, Sussex, UK).

Design: This was a pilot study with randomized, single-blind, cross-over design (baseline, two treatment periods, and a washout period, each of 1 week duration).

Subjects and setting: Volunteers with defined insomnia treated on a domiciliary basis participated in the study.

Outcome measures: Outcomes were assessed with the following: Pittsburgh Sleep Quality Index (PSQI) indicating insomnia (score >5 at entry); Borkovec and Nau (B&N) Questionnaire evaluating treatment credibility; and Holistic Complementary and Alternative Medicine Questionnaire (HCAMQ) assessing attitudes to CAM and health beliefs.

Results: Ten (10) volunteers (5 male and 5 female) were entered and completed the 4 week study. Lavender created an improvement of −2.5 points in PSQI ($p = 0.07$, 95% CI −4.95 to −0.4). Each intervention was equally credible and belief in CAM did not predict outcome. Women and younger volunteers with a milder insomnia improved more than others. No period or carry-over effect was observed.

Conclusion: The methodology for this pilot study appeared to be appropriate. Outcomes favor lavender, and a larger trial is required to draw definitive conclusions.

INTRODUCTION

Insomnia, defined as the subjective dissatisfaction with the duration or quality of sleep, is the most common of all sleep complaints.[1,2] Clinically it affects 5–10% of persons >25 years and >35% of those aged ≥65 years.[3] Surveys indicate that in any given year, one third of the adult population will report some degree of insomnia.[4] Despite the prevalence of insomnia and the distress it causes to so many individuals, it remains one of the most neglected areas of sleep research.[†] It has been estimated that approximately 75% of persons with chronic insomnia attribute the start of

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their sleep problems to a stressful life event.[5,6] No currently available drug induces normal sleep; and all have drawbacks, such as tolerance, dependency, withdrawal reactions, and hangover effects.[7] Currently, hypnotic agents are the treatment of choice and are frequently prescribed long term despite recommendations that they are for short-term use only.[8–10]

With the increasing popularity of complementary and alternative medicine (CAM)[11] there has been a concomitant increase in the number of CAM practitioners; aromatherapy is one of the most rapidly expanding areas, involving approximately 20,000 therapists.[12] The most recent systematic review on aromatherapy by[13] identified 12 clinical trials. The studies were underpowered, demonstrating poor methodology in areas such as outcome randomization and blinding. Cooke and Ernst examined the use of aromatherapy in combination with massage; yet the authors' conclusions tended to relate to aroma alone. In response, Vickers published an editorial identifying studies that had shown considerable evidence that massage alone had an anxiolytic effect.[14] The literature search for the current study used PubMed and CISCOM databases and identified eight randomized controlled trials using aroma alone compared to placebo.[15–22] These studies varied greatly in subject numbers (4–313) and had poorly described methods. None evaluated the blinding of the placebo/control intervention (or equipoise) in relation to odor. Belief in CAM and other potential predictors of outcome (age, gender, and illness severity) were not routinely reported, nor was the dose–response effect from aroma. Five of these eight studies used lavender as an anxiolytic; none evaluated the claim that it may have a hypnotic effect. The evidence for the specific efficacy of aromatherapy alone is therefore incomplete, complex, and confusing, and there is no more than anecdotal evidence for its use as a hypnotic.

The current study develops previously unpublished work within the authors' departments that suggests that lavender may have a hypnotic effect, although its possible mechanisms of action are speculative and unclear. The main aim of this pilot study is to look at the feasibility of the proposed clinical trial methodology, specifically the choice of control/placebo oil, duration of treatment and washout periods, and potential period and carry-over effects. An estimatation of sample size for a more definitive study, as well as possible predictors of outcome, is also planned.

METHODS

This was a single-blind, randomized, controlled crossover pilot study of lavender oil versus sweet almond oil (placebo/control) delivered by an Aromastream vaporizer (Tisserand Aromatherapy, Sussex, UK). The study involved the recruitment of 10 otherwise healthy volunteers, and there was no basis on which to make a power calculation. Ethics approval was obtained from the Southampton Local Research Ethics Committee (No. 338/03/w).

Entry criteria

Subjects were entered into the study if they were experiencing established insomnia evaluated by the Pittsburgh Sleep Quality Index (PSQI) with a global score of >5 at study entry. Previous insomnia history was not evaluated at entry and represented neither an inclusion nor an exclusion criterion for patient selection. Subjects were required to be healthy and between 18 and 50 years of age. They were excluded if they were pregnant (or planning to become pregnant), were acutely ill, had previously experienced sensitivity to aroma oils, had a systemic illness affecting their sleep or a previously diagnosed pathologic sleep condition, had recently used aromatherapy, or were taking short-term medication that might affect their sleep patterns.

Recruitment

Advertisements for this study were circulated by the University network and local teletext. A preliminary telephone interview was then conducted for those individuals who responded, to ascertain whether they fulfilled the inclusion criteria. All subjects fulfilling these criteria and wanting to be included in the study were invited for a medical consultation to confirm suitability, exclude other serious illness, receive an explanation of the study, and give informed consent.

Study design

The first phase (A/B) of the trial consisted of a 1-week baseline period with no treatment and assessments at the beginning (A) and end (B) of the run-in week (Fig. 1). Subjects who still recorded a PSQI >5 at the end of baseline were randomized into two groups (1 or 2), which determined the order of treatment. Patients in group 1 received treatment 1 (lavender oil) the treatment 2 (almond oil), whereas those in group 2 received the treatments in the reverse order. The treatment codes were not broken until after the analysis had been completed. Phase C was 7 nights of exposure to the first aroma oil, Phase D a 7-night washout period, and Phase E 7 nights of exposure to the second oil. All subjects participating in the study used the aroma and aromastream in their own homes. Contact with the investigator was made by telephone.

Interventions

Tisserand Aromatherapy provided *Lavandula augustifolia* and sweet almond oil free of charge for this study. The two interventions were bottled identically and the bottles sealed so that no aroma could be smelled. The bottles were labeled Treatment 1 and Treatment 2 and were self-administered by the volunteers, with the order determined by the

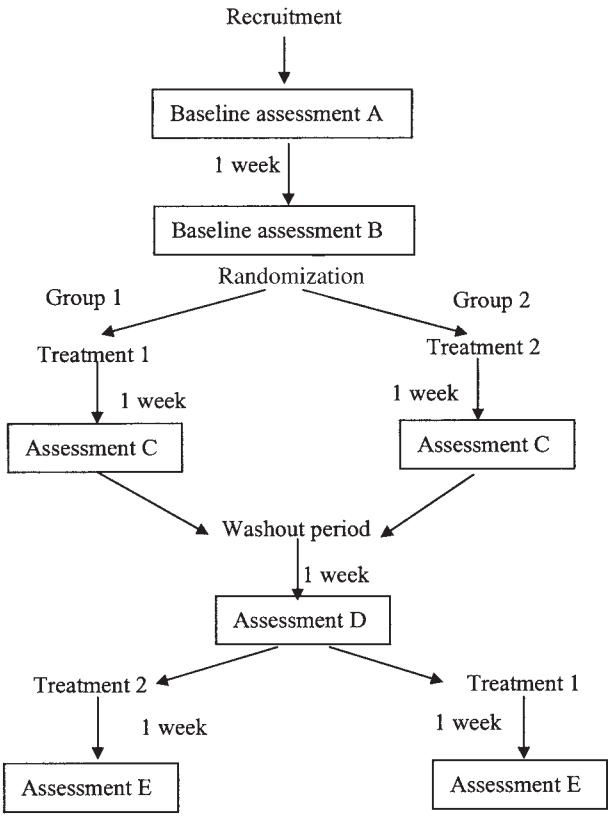

FIG. 1. Study design.

randomization. A new aroma cartridge was used for each of the treatment periods and 6–8 drops of each oil were added each night to the cartridge, as recommended by Westwood[23] and Worwood.[24] The Aromastream was then activated and vaporized the aroma continuously overnight. It is recognized that no reliable measure of treatment compliance was possible in this pilot study. The study population did not receive any information on sleep hygiene. The treatment was self-provided in the patients' own homes and as such may have been uncontrolled and not standardized.

Lavandula augustifolia is sourced organically in the foothills of the Pyrenees. The flowers from the lavender plants are put into large stainless steel containers. Water is heated in a separate chamber to create steam and then passed through the plant material, breaking it down so the essential oil is released as a vapor at 5–6 atmospheres. When the pressure is released from the system, the steam vapor enters a cooling chamber and the hot water is decanted off, leaving the insoluble hydrosol as 100% pure essential oil. Almond oil is manufactured by cold-pressing organically grown almond meal with a high-pressure cold press and subsequently filtering and using the oil produced.

Randomization

A computer program was used to randomize the order of the two treatments for the 10 patients. The coded sequences were then placed in sealed opaque numbered envelopes, which were opened in numerical order as the subjects entered the study.

Outcome measures

PSQI. This was the primary outcome measure, which was completed at the beginning of the study by volunteers satisfying the inclusion criteria and at the end of each weekly period. The PSQI is the most commonly used and best validated self-rated questionnaire available to measure sleep quality and sleep disturbance. It consists of 19 questions grouped into seven component scores, which yield a global PSQI score ranging from 0 to 21 points (0 indicating no sleep difficulty, 21 indicating severe sleep difficulty). Subscores were ignored for the purpose of this study and the more robust total PSQI was taken as the primary outcome. A total PSQI >5 indicates poor sleep quality. A PSQI improvement of 3 points on the global score is regarded as a clinically significant improvement in sleep disturbance.[25,26]

HCAMQ. The Holistic Complementary and Alternative Medicine Questionnaire [HCAMQ] is a validated questionnaire[27] consisting of 12 items. Six relate to beliefs about the scientific validity of CAM and six relate to holistic health. Responses were scored on a 6-point Likert scale (strongly agree, 1 to strongly disagree, 6); a low score shows sympathy to CAM. We evaluated whether attitudes to CAM and holistic health beliefs predicted outcome.

Borkovec and Nau (B & N) questionnaire. The B & N questionnaire assesses treatment credibility as a surrogate for blinding.[28] A double-blind study cannot be conducted because of the individual scent of lavender, so it was important to be sure that each treatment was equally credible and that patients were in equipoise. The B & N questionnaire contains four items, each scored on a 6-point Likert scale (no confidence, 1, to very confident, 6). Questions 1 and 2 were asked before treatment and questions 3 and 4 immediately after treatment. The B & N questionnaires were completed before and after the 1st week of treatment week and before and after the 2nd week of treatment. Questions were as follows:

Q1: How confident do you feel that this treatment can alleviate your complaint?
Q2: How logical does this treatment seem to you?
Q3: How confident would you be in recommending this treatment to a friend who suffered from the same complaint?
Q4: How successful do you think this treatment would be in alleviating other complaints?

Statistical analysis

Changes in the PSQI score from baseline to the end of the first treatment period were evaluated for each subject and

compared with the corresponding changes from washout to end of the second treatment period using an analysis of variance (ANOVA) appropriate for a cross-over design. This analysis estimates and compares the within-subject treatment differences allowing for possible differences in PSQI caused by the sequence order of the treatments for the two groups of subjects. The analysis also estimates and assesses whether there is any evidence of a differential carry-over effect of the treatments from the first to the second treatment period. The B & N was evaluated with serial Wilcoxon tests. The HCAMQ data were correlated with PSQI change and were analyzed using linear regression (NCCLS EP6-P). Analysis was carried out before to breaking the randomization code.

RESULTS

All subjects entering the study completed 2 weeks of randomized treatment and 4 weeks of data collection, including one week of untreated run-in and one week washout between the two 1-week treatment periods. Figure 2 shows the patient flow for the study.

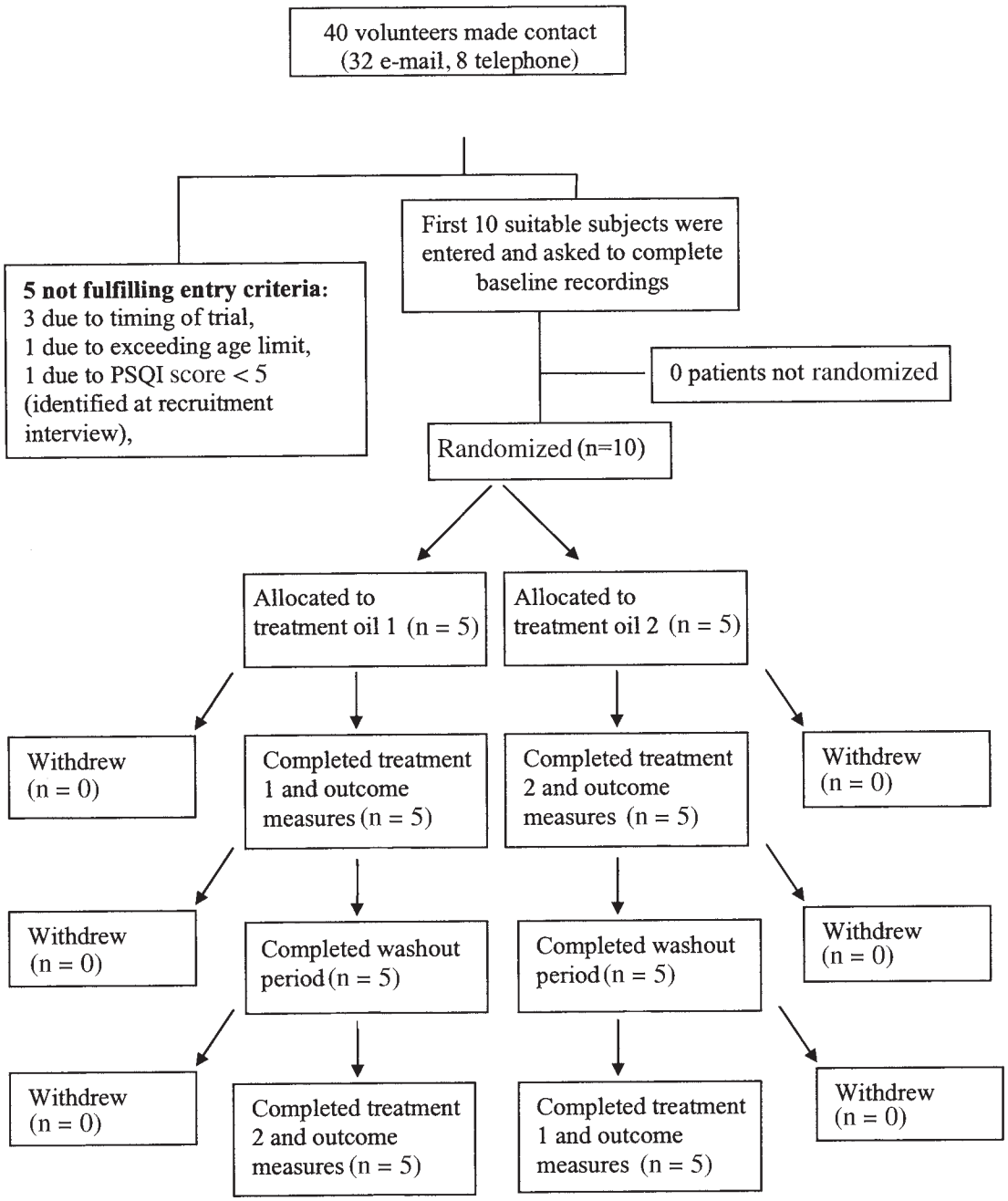

FIG. 2. Consort for study.

Table 1. Comparison of Sex, Age, and Entry PSQI Score Between Groups

	Group 1			*Group 2*		
	Mean	*Median*	*SD*	*Mean*	*Median*	*SD*
Sex		2 Female: 3 Male			3 Female: 2 Male	
Age (years)	37.4	39	7.02	40.4	42	4.56
Entry PSQI	12	13	4.12	12	12	3.32
HCAMQ total	37.2	38	1.64	36.6	37	2.51
CAM score	25.2	25	1.30	23.8	23	2.17
HH score	12	11	1.41	12.8	12	2.49

The Holistic Complementary and Alternative Medicine Questionnaire (HCAMQ) contains two subscores. These are the CAM belief score (CAM Score) and the Holistic Health Score (HH Score).

CAM, complementary and alternative medicine; PSQI, Pittsburgh Sleep Quality Index; SD, standard deviation.

Comparison of treatment groups

Table 1 shows the mean ages, gender division and baseline means for PSQI and HCAMQ (total and subscores relating to belief in CAM and Holistic Health [HH] beliefs), for the two groups of patients. These were well matched for all possible known confounders.

PSQI outcomes

PSQI scores at entry (A) compared to PSQI at the end of the baseline period (B) showed no overall change. One subject maintained the same PSQI, four subjects reported an increase in insomnia, and five subjects reported a decrease in insomnia. There was an average improvement of +0.4 in PSQI from the first to the second baseline assessment ($p = 0.51$).

Table 2 shows the mean PSQI scores for the two treatment sequence groups at the different assessment periods AB is the average baseline score; whereas C, D, and E are the mean scores after the first treatment, washout and second treatment periods respectively. A within-subject crossover ANOVA of these results indicates a nearly significant treatment difference of −3.1 ($p = 0.07$, CI −6.5 to 0.3) between the changes in PSQI in favor of lavender oil, but no period difference (0.2, $p = 0.89$, CI –3.2 to 3.6) or any evidence of an interaction or carry-over effect (−0.7, $p = 0.55$, CI −4.8 to 3.4) of either treatment from the first to the second treatment period.

The individual responses to lavender oil are shown in Figure 3. There were clinically significant improvements (PSQI >3) in subjects 1, 4, 7, 8, and 10. The average group PSQI change with lavender was −2.5 ($p = 0.07$, CI −4.95 to −0.04). There was no statistically significant difference between PSQI scores for either treatment groups in response to sweet almond oil; in fact there appeared to be a slight increase of 0.2 in PSQI with almond oil ($p = 0.8$, 95% CI −1.4 to 1.8).

Possible confounders

There was a slight difference in response to lavender oil according to age. The five older individuals (>39 years) had a less marked response to lavender (an improvement of 1.4), whereas the younger age group (<39 years) improved by an average of −3.6 ($p = 0.08$, 95% CI −7.9 to 0.67). There was an initial pretreatment difference between the genders, with women having an average PSQI score pretreatment of 3.6 units lower than that in men. The female response to lavender oil is greater than the male response, with women recording an average decrease in PSQI of −4.6 units ($p = 0.37$, 95% CI −8.77 to −0.42). Those with a PSQI score >12 at entry showed little response to lavender, but those

Table 2. Means of PSQI for the Two Treatment Sequence Groups at Baseline, First Treatment, Washout, and Second Treatment

	Period 1				*Period 2*		
	Treatment sequence	*Baseline A, B*	*Response C*	*Difference*	*Washout D*	*Response E*	*Difference*
			Treatment 1 (lavender oil)			*Treatment 2 (almond oil)*	
Group 1	1/2	11.9	9.2	−2.7	9.6	9.8	0.2
			Treatment 2 (almond oil)			*Treatment 1 (lavender oil)*	
Group 2	2/1	11.7	12.8	1.1	12.4	10.2	−2.2

PSQI, Pittsburgh Sleep Quality Index.

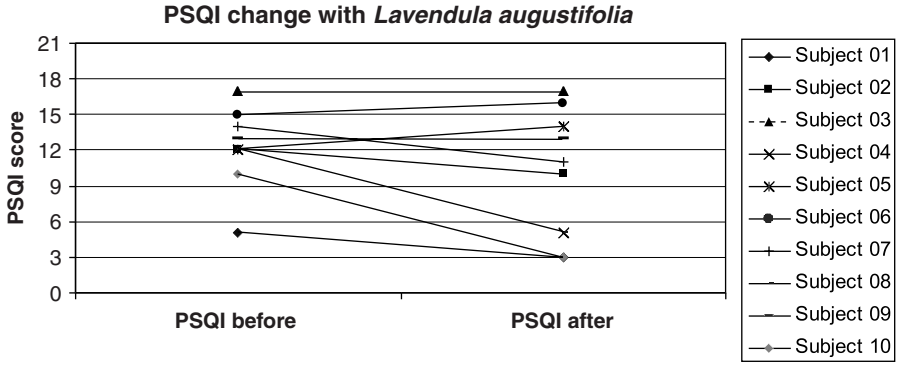

FIG. 3. Individual response to *Lavandula augustifolia*.

with a PSQI <10 at entry improved by an average of −5 units during the study ($p = 0.015$, 95% CI −8.4 to −1.59).

B & N questionnaire

Before pretreatment, subjects were less confident that lavender oil would help than they were about sweet almond oil ($p = 0.05$, Wilcoxon test). Both treatments appeared equally logical. Post-treatment, in the answers to questions 3 and 4, lavender oil was significantly more likely to be recommended as a treatment for insomnia ($p = 0.025$, Wilcoxon test) and more likely to be successful in treating other complaints ($p = 0.025$, Wilcoxon test).

HCAMQ

Attitudes toward health and belief in CAM showed no significant or nearly significant predictive value of outcome as measured by the PSQI.

Aromastream device

Tisserand's aromastream device was found to be noisy by 70% of volunteers in this study. The subjects who were troubled by the noise indicated that the Aromastream itself caused sleep disturbance. As a consequence, these seven individuals switched the Aromastream off on retiring to bed, having left it on for 1 hour before they planned to go to sleep for the night. The planned duration/dose of treatment was therefore not delivered.

DISCUSSION

This pilot study demonstrates that this approach to evaluating aromatherapy with lavender for insomnia is appropriate. The cross-over study model appears to be effective, with no evidence of any carry-over effects. The duration of treatment and dose of lavender appear to create a clinically significant effect in a substantial number of the volunteers, but because of the failure of the aromastream to be used as intended in this context, an even greater clinical effect may have been observed with a greater and more consistent dose of lavender. Different methods for delivering a more consistent dose of the aroma through the night must therefore be considered. It may also be that a longer duration/dose might create a more sustained, long-term hypnotic effect.

The study findings almost reached statistical significance. Therefore, the study provided a good basis on which to estimate a sample size. It appears that 11 individuals would be needed for this study design to obtain an 80% power at 5% significance, using an improvement of 3 units in the PSQI score as clinically significant. However, 20 individual volunteers would be preferable, to be sure of running a definitive study. Women with mild insomnia responded far better to lavender than any other treatment group. It is not clear whether it was gender or severity that predicted outcome, but both should be stratified in any future study. Belief in CAM and attitudes toward health do not predict outcome, so these should not be used in the future.

It is noteworthy that there was no hypnotic effect from entry into the study during the baseline period and that there was also no placebo or nonspecific effect of almond oil recorded. Clinical effects from both these interventions were expected, and it will be fascinating to see whether this observation is duplicated in a larger study.

Equipoise is a real issue in placebo-controlled trials of aroma, particularly with easily recognized aromas such as lavender. It is possible that the distinctive odor of lavender promotes pleasant recollections or that it may be known to have a beneficial effect on insomnia. Through odor memory or even the exposure to a pleasing ambient odor, positive emotions may be evoked, and thus pleasant feelings could be inherent in its hypnotic effects. In this pilot study, subject 1 found "the smell [of lavender oil] unpleasant," and yet recorded clinically significant enhanced sleep quality, which suggests the opposite. In any future study one must be sure that volunteers completing the B & N scale have smelled the odor of each oil before completing the questionnaire. In this study it was not absolutely clear whether this occurred, as patients took home both the B & N scale and the aroma oils, and not enough instructions about the "order" of this process

was provided. Patients may have scored the B & N Credibility Scale either before or after smelling the two aroma oils. If they believed that lavender might be associated with a positive clinical effect, this might have biased the outcomes of the credibility measurements. In future trials, patients should smell the oils prior to rating their credibility.

CONCLUSIONS

The field of aromatherapy is the most rapidly growing area of CAM in the United Kingdom, but little evidence exists for the efficacy of aroma alone. The method and results described appear to hold promise and suggest that a randomized, single-blind, cross-over trial with a washout period could be effective in evaluating lavender as a hypnotic agent for mild insomnia.

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