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A Novel Natural Sleep Aid Formulation: A Pilot Clinical Trial

Sleeping Beauty by Henry Meynell Rheam

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Abstract

A pilot clinical trial was performed on 25 participants who had a history of sleep concerns. A proprietary blend of four essential oils in an organic Jojoba (*Simmondsia chinensis)* oil carrier, referred to going forward as the "Sleep Aid Formulation," was topically applied prior to retiring to sleep. Sixty percent of the subjects of this study found the Sleep Aid Formulation helpful in addressing more than one of the sleep problems identified, and the overall indication was that there was greater than a 90% chance that the Sleep Aid Formulation users would experience some relief from the indicated sleep problems after repeated application. User feedback and results were acquired using detailed questionnaires.

Introduction

According to the National Sleep Foundation, 60% of American adults experience some degree of sleep problems almost every night. This amounts to approximately 100 million people just in the U.S. Some of these subjects turn to pharmaceutical over-the-counter (OTC) or prescription drugs as a treatment option. However, long-term use of various medications has been linked to adverse outcomes in overall health (Chong et al, 2013; National Institutes of Health, no date).

In addition, the Centers for Disease Control (CDC) and Prevention has declared insufficient sleep as a public health epidemic (CDC, 2014). According to the Division of Sleep Medicine at Harvard Medical School, chronic sleep deprivation has been linked to obesity, cancer, heart disease, high blood pressure, diabetes, lowered immunity and neurological problems, all of which drastically reduce quality of life (Harvard Medical School, 2007).

Another landmark study conducted by University Hospitals Case Medical Centre researchers found that, over time, a lack of sleep has the effect of drastically accelerating the signs of skin aging.

Not only does poor sleep add to physical stresses and strains, but it affects every psychological aspect of people's lives: their relationships, their creativity, the way they feel and their productivity.

It has been known for many centuries that essential oils can have significant physical and psychological effects on humans, both positive and negative, and many individual oil extracts have been studied (Hongratanaworakit, 2004) and used by different civilizations for their beneficial and sometimes deleterious effects.

It is now generally accepted that Aromatherapy can have a beneficial effect on several different human conditions, including sedative effects (Buchbauer et al, 1993).

We have identified a number of herbal essential oils and blended them in proprietary mixes to obtain these beneficial effects. In the particular case of the Sleep Aid Formulation, this blend contains, among other materials, Sandalwood (*Santalum album*), Ylang-Ylang (*Cananga odorata forma*), Palmarosa (*Cymbopogon martini* var. *martini*) and Vetiver (*Vetiveria zizanioides*) essential oils.

Materials and methods

The Sleep Study Enrollment Questionnaire was used to select 25 subjects (male and female, age 25 or older). The potential test subjects were selected for having difficult sleep behaviors, consisting of one or

more of the following symptoms:

- difficulty in falling asleep at night (more than 30 minutes)
- falling asleep reasonably quickly but waking up once or more in the middle of the night with difficulty in resuming sleep
- sleeping four or five hours continuously but then waking up and not being able to fall asleep again

Once selected, these 25 test subjects completed a two-week Pilot Clinical Trial. The objective was to have at least six subjects for each of the above categories.

Inclusion criteria of entry into the study

- Sex: Males or females
- Age: 25 years or older
- Health: Subjects in good health with no skin disease
- Subjects will fill an entry questionnaire to be provided by the sponsor
- Informed consent: Subjects must read and sign the Informed Consent form after the nature of the study and evaluations have been fully explained

This was an open-label methodology study with no comparative product to be co-evaluated. One container with the formula was provided to each participant, and they were requested to apply the proprietary Sleep Aid Formulation according to instructions.

The directions were as follows:

- Apply liberally to temples, wrists and neck one-half hour before retiring to sleep. For maximum results, also dab under nose and inhale deeply. Reapply just prior to sleep to promote a good night's sleep.

All the subjects visited the study site at enrollment and again after two weeks of using the product daily as directed. During each of these visits, they filled out a questionnaire (Figures 1 and 2). They were also interviewed and had their skin clinically examined for signs and symptoms of irritation from the investigator.

The objective was to assess whether the properties of the essential oils within the blend benefited the users by helping them with their sleep difficulties. The outcomes were quantified on a scale of 1–5, assessing product efficacy with a score of "1" to indicate no relief and scores of "2–5" to indicate increasing levels of relief.

Sleep Study Enrollment Questionnaire

Sex: Male Female Age: ……..y.o.

1. You have been invited to participate in this study because you indi cated that you have sleeping problems. Is this correct?
   Yes No
   (If NO is selected, please terminate interview)

2. Please indicate what kind of sleeping problems you have, using a scale of "1: no problem at all" to "5: very much so"

a) Difficulty in falling asleep at night
b) Falling asleep but waking up several times in the middle of the night
c) Falling asleep but waking up after 4 or 5 hours and then staying awake

3. For how long have you had the problem(s)?
4. Are they related to any special personal circumstance? (please explain)
5. Have you used any Aromatherapy product before?
6. Are you allergic to any kind of fragrance?

Figure 1. Sleep Study Enrollment Questionnaire

Sleep Aid Final Questionnaire

Participant No.:…….. Initials:……

Please respond to the following questions using a scale of "1: no prob lem at all" to "5: very much so"

1. How did you like the product?
2. Was the fragrance acceptable?
3. Did the product feel good on your skin?
4. Did the product feel oily?
5. Did the product absorb quickly?
6. Did the product help in falling asleep at night?
7. Did the product avoid your waking up several times in the middle of the night?
8. Did the product help you sleep longer hours without waking?

If your sleeping problem was associated with any special personal cir cumstance, did this situation change during the study? (please explain)

Did you use any other sleeping aid during the study? If so, which one?

Figure 2. Sleep Study Final Questionnaire (at conclusion of the two-week study)

For statistical analysis, the scores were then treated as a binomial population, namely, relief (scores from "2–5") or no relief (score of "1").

Other questions asked (Q5–Q8 on the Sleep Study Enrollment Questionnaire and Q1–Q5 on the Sleep Aid Final Questionnaire) were in regard to the specific cosmetic attributes of the Sleep Aid Formulation and deal with other topics which could have

influenced the subjects' reported change in sleep patterns. These answers were noted and explored in the Discussion.

Test product

The selection of essential oils for the Sleep Aid Formulation were chosen to address various components of insomnia: restlessness, active mind, racing heart and quickness of breath.

The test product consisted of a blend of essential oils (4% total) in an organic Jojoba carrier oil (96% total). The product was provided to the clinical investigator in 0.27 oz (8 ml) roll-on glass containers. The product contained:

Simmondsia chinensis (Jojoba) seed oil (batch 2013)
Santalum album (Sandalwood) wood oil (batch#105)
Cananga odorata forma (Ylang-Ylang) flower oil (batch #104)
Cymbopogon martini var. *martini* (Palmarosa) grass oil (batch#106)
Vetiveria zizanioides (Vetiver) root oil (batch#103)

Essential oils used

Sandalwood causes an increase in alpha-wave activity in the human brain (Hongratanaworakit et al, 2003), and thus has a sedating and soothing effect on the nervous system. It was found that its aroma has a way of quieting the mind and settling the breath.

Ylang-Ylang has proven its ability to slow a rapid heartbeat (Cha et al, 2010). It is relaxing to the central nervous system (CNS) (Hongratanaworakit et al, 2006) and has been shown to help regulate adrenaline flow and cortisol levels (Kim et al, 2012). Thus it had been used to reduce anxiety, anger, shock, panic and fear, thus relieving insomnia, nervous tension, stress palpitations (Hongratanaworakit et al, 2002) and blood pressure (Hongratanaworakit et al, 2004).

Palmarosa has wonderful antiseptic and antifungal properties, but in this context, it was chosen for its soothing and calming effect on smooth muscles and contractions and its neuro-protective effect against oxidative stress (Buch et al, 2012) which contributes to its overall relaxing effects.

Vetiver, known as the "Oil of Tranquility," has been recognized for centuries as a wonderful tonic for the entire body, including the digestive, nervous, endocrine, immune, respiratory, circulatory, neurotic, and excretory systems (Singh, 2010). The oil has been shown to lower heart rates and ease rapid breathing (Arzi et al, 2010), while helping the respiratory system return to a calm state. Vetiver's qualities as a tonic for the nervous system make it effective as a sedative, soothing states of irritability and anger (Nagai et al, 1991).

Results

Fifteen out of twenty-five subjects (60%) in this study found that the Sleep Aid Formulation helped to relieve one or more of the sleep problems they suffered from and identified in their Sleep Study Enrollment Questionnaire. While the p-value (0.0974) in this assessment was formally found not to be statistically significant ($p<0.05$), the indication was a greater than 90% chance that the Sleep Aid Formulation user would experience some level of relief from sleep problems after repeated application of the product.

Efficacy also seemed to differ in subjects with different types of sleep problems (Tables 1–3), with the greatest efficacy found in the group whose primary problem was first falling asleep at night (Table 1). In this group, formal statistical significance was almost achieved, since the p-value was 0.0703, practically at the requisite p=0.05 or less. It is likely that had the study enrolled a larger number of subjects, their responses would have reached statistical significance.

Subject's Number	2	3	4	8	12	13	17	21	22
Q1* How did you like the product?	2	4	4	4	5	5	3	2	1
Q7* Helped falling asleep	1	5	4	3	5	4	2	2	1
Q8* Helped avoid waking in the middle of the night	1	5	5	4	5	1	1	1	1
Q9* Helped to sleep longer hours without waking	1	4	5	1	5	5	1	1	1

Table 1. For subjects with difficulty first falling asleep at night:

- Q1, Q7, Q8, Q9: Questions 1, 7, 8, & 9: Sleep Aid Final Questionnaire.
- **7 of 9 subjects in this sub-group experienced relief in falling asleep (Q7).
- Like/dislike scores and three assessments of the efficacy of Sleep Aid Product after 14 days of use.
- Scores from questionnaire responses, using a scale of "1= not at all" to "5= very much."
- A score of "1" indicates no relief; scores of "2–5" show increasing levels of relief.**
- By binomial analysis (relief/no relief), this was practically significant with p=0.0703.

Subject's Number	1	9	10	11	14	15	18	24
Q1* How did you like the product?	3	5	5	1	4	1	1	5
Q7* Helped falling asleep	2	5	5	1	4	1	1	5
Q8* Helped avoid waking in the middle of the night	2	5	5	1	5	1	1	5
Q9* Helped to sleep longer hours without waking	2	5	5	1	1	1	1	5

Table 2. For subjects who fell asleep, but woke up repeatedly during the night:

- Q1, Q7, Q8, Q9: Questions 1, 7, 8, & 9: Sleep Aid Final Questionnaire.
- **5 of 8 subjects in this sub-group experienced relief in awakening repeatedly during the night (Q8).
- Like/dislike scores and three assessments of the efficacy of Sleep Aid Product after 14 days of use.
- Scores from questionnaire responses, using a scale of "1= not at all" to "5= very much."
- A score of "1" indicates no relief; scores of "2–5" show increasing levels of relief.**
- Not statistically significant, by binomial analysis (relief/ not relief) p=0.2188.

Subject's Number	5	6	7	16	19	20	23	25
Q1* How did you like the product?	5	1	1	1	1	4	3	1
Q7* Helped falling asleep	5	1	1	1	1	5	3	1
Q8* Helped avoid waking in the middle of the night	4	1	1	1	5	5	3	1
Q9* Helped to sleep longer hours without waking	5	1	1	1	1	5	3	1

Table 3. For subjects with difficulty falling asleep again, having awoken during the night:

- Q1, Q7, Q8, Q9: Questions 1, 7, 8, & 9: Sleep Aid Final Questionnaire.
- **3 of 8 subjects in this sub-group experienced relief in falling asleep again, having awoken during the night (Q8).
- Like/dislike scores and three assessments of the efficacy of Sleep Aid Product after 14 days of use.
- Scores from questionnaire responses, using a scale of "1= not at all" to "5= very much."
- A score of "1" indicates no relief; scores of "2–5" show increasing levels of relief.**
- Not statistically significant, by binomial analysis (relief/ not relief) p=0.2188.

Discussion

The overall result of 60% of the study's participants experiencing an improvement of sleep quality confirms the Sleep Aid Formulation's efficacy and suggests that it could be a non-drug alternative to addressing the problem of sleep deprivation in our modern society.

There were a few participants who did not like the scent of the blend (most likely the Vetiver component, which some people find distasteful) and did not report any improvement in their sleep quality. It should be noted that it is important that the subject like the scent of the essential oil blend for it to be effective. Those participants who disliked the scent also did not use as much of the blend as the other participants and had more product left at the end of the study, possibly another reason why the product was less effective in their cases.

The application of a roll-on essential oil blend is a natural alternative to using pharmaceutical medication when addressing sleep problems. All OTC and prescription sleeping pills have side effects (National Institutes of Health), which can vary depending on the specific drug, the dosage and how long the drug lasts in the patient's system. Common side effects include headaches, muscle aches, constipation, dry mouth, daytime sleepiness, trouble concentrating, dizziness, unsteadiness and rebound insomnia. The essential oils in this Sleep Aid Formulation generally have no known negative side effects. They are gentler on the body and mostly pleasant to the user as compared to more aggressive pharmaceuticals.

Roll on bottle
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Using plant-based essential oils for this purpose is a safer and more organic option. In addition to acting as a sleep aid, the essential oils in this Sleep Aid Formulation also have other wonderful healing benefits that actually complement the user's overall health and wellness (Hongratanaworakit, 2004; Nagai et al, 1991).

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