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Research Report to Evaluate the Effectiveness of 5 Aromatherapy Formulations on the Quality of Sleep

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Please note this is an extract from the full research paper and adapted to suit our magazine. For the full paper please contact Miracle Plant. You can find their details at the end of this article.

Introduction to Sleep Disorder

Sleep disorders are a serious health and public health problem in today's society, mainly manifested as insomnia, sleep-related breathing disorders, excessive sleepiness and parasomnias, and so on,[1] which seriously affects people's daily life, work and physical and mental health, and is closely related to cardiovascular and cerebrovascular diseases, malignant tumors, and psychological diseases. [2] According to clinical statistics, about 10% to 20% of adolescents and adults suffer from insomnia, and the incidence of sleep disorders in the elderly is 30% to 40%. Nearly 90% of the elderly experience sleep problems such as difficulty falling asleep, waking up early or increasing the number of awakenings, etc.[3] Although insomnia is not a critical illness, long-term insomnia not only seriously affects people's work and quality of life, it is also an important risk factor for mental and psychological diseases, cardiovascular diseases, and diabetes, which increases the medical burden of society.[4,5] Therefore, it is necessary to actively pay attention to sleep problems and seek practical and effective treatments. At present, the clinical treatment methods for sleep disorders are mainly drugs, behavioral cognitive therapy, and traditional Chinese medicine.[6] In the pharmacological treatment of insomnia, the guide recommends the first choice of short and medium-acting benzodiazepine receptor agonists or melatonin receptor agonists, as well as antidepressants with sedative effects. [7] However, it generally suffers from adverse reactions such as addiction, cognitive and mental impairment, respiratory depression, affecting the quality of daytime awakening, and so on, and it is resistant to drugs and easily causes rebound.

Research Design and Method

With the progress of the times, people's quality of life has gradually improved, but with the pressure of work and the fast pace of life, many physical and mental diseases have arisen, among which insomnia is the most common, and insomnia has become a serious health problem for modern people. Therefore, through this clinical experience, "the use of compound aromatherapy", to evaluate the improvement of the sleep quality of the subjects.

This study conducted a cross-validation clinical comparison through a simple and accurate Pittsburgh Sleep Quality Index (PSQI).[9] The Pittsburgh Sleep Quality Index (PSOI) is a self-rated questionnaire which assesses sleep quality and disturbances over a 1-month time interval. It is expected that data such as the time required for improvement and the degree of improvement will be obtained at the end of the experiment. The current traditional measurement of sleep "the quickest and easiest way to improve quality" is through the Pittsburgh Sleep Quality Index (PSQI) published by Buysse. This method is scientific and easier for subjects to grasp and answer relevant questions. It is currently the most commonly used for evaluating improvement of sleep quality.

This experimental questionnaire takes the PSQI published by Buysse et al. as a reference template. The content of the questionnaire is mainly to review the sleep profile of the subjects in the previous month, which includes 7 elements:

· sleep quality

- sleep latency
- hours of sleep
- sleep efficiency
- sleep disturbance
- Use of sleeping pills or related supplements
- Daytime functioning

The effectiveness assessment study was performed in 2022 on more than 250 volunteers in 5 separate groups. The study aimed to investigate the effect of testing aroma formulations on 5 different groups, including for everybody, kids, mature, her and him. 5 randomized-placebo-controlled studies providing aromatherapy with effective aroma spray as an intervention were conducted according to different group. The outcomes were assessed under PSQI questionnaire assessment calculation scores.

Written informed consent was obtained from each volunteer to participate in the study. Samples were selected by the convenient method and then randomly classified into two groups of intervention and control.

To collect the data in this study, two questionnaires were used, one of which includes personal profile, and the second questionnaire is the Pittsburgh Sleep Quality Index (PSQI).

Testing Samples

The "Aroma Perfume in spray format" are formulated for the purpose of improving sleep quality in 5 different application areas.

- (1) The product line contains 5 formulas that are suitable for
- 1.1) all (for Every Body, ages 25 to 50).
- 1.2) women (for Her, ages 25 to 50).
- 1.3) men (for Him, Ages between 30 and 50).
- 1.4) Mature (for Mature, suitable for people aged 60 and above).



1.5) Children (for Kids, between 3 months and 12 years old).

All formula combinations are made with 100% natural ingredients. All formulas are designed by aromatherapists.

- (2) Subject to classification for research purposes, participants will only be selected in one of the appropriate product categories.
- (3) Australian-made "Aroma Perfume" is a natural aromatherapy perfume designed to improve sleep, made from 100% natural ingredients. Miracle Plant Deep Sleep Natural Perfume is designed to provide sleep solutions for all.
- (4) Regardless of the product category, product is easy to use. Gently spray 1-3 times on pillows, sheets, pajamas or around the room. The exclusive aromatherapy fragrance will help you relax and rejuvenate in a deep sleen.
- (5) The main ingredients of five categories of aromatherapy perfume formulations:
- For "Her" Geranium, Sandalwood, Frankincense, Lavender
- For "Him" Frankincense, Sandalwood, Petitgrain, Patchouli
- For "Mature" Orange, Vetiver, Cedar, Lavender
- For "Kids" Mandarin, Lavender
- For "Every Body" Lavender,
 Sandalwood, Frankincense, Mandarin

Data Analysis and Interpretation

Data analysis

The PSQI was developed by Daniel J. Buysse and collaborators to measure quality of sleep and to help discriminate between individuals who experience poor sleep versus individuals who sleep well. The scale has several domains, which include subjective sleep quality, sleep latency, sleep duration, habitual

sleep efficiency, sleep disturbances, use of sleep medication, and daytime dysfunction.

Most of the items are organized in multiple choice questions and are brief and easy to understand and answer. The PSQI questions are rated from 0 = no difficulty to 3 = severe difficulty, generating scores that correspond to the domains of the scale. The scores range from 0 to 21. The lowest score of sleep disorder is 0, which is interpreted as lack of sleep disorder; and the highest score is 21, which indicates the highest rate of sleep disorder

The data were analyzed in reference to SPSS 18 methodology, and PSQI scoring system then modify them into a unique scoring system. The final data presented as score in %.

Experiment procedure

In this experiment, some subjects were invited to engage a clinical effectiveness assessment. At the beginning, subjects were required to fill in the PSQI questionnaire before experiment to start and covering 7 topics according to the sleep profile of the previous month. When subjects completed the experiment, they re-fill another PSQI questionnaire. Finally, analyze the data one by one, make statistics, observe the measurement results of participants, and observe whether the score of the algorithm for calculating sleep quality by comparing before and after the experiment is correlated with the total score of the PSQI questionnaire.

"For Every Body" Group: Results and Interpretations

The study attempted to recruit 50 subjects initially. Seven subjects withdrew from the study due to not following the standard instruction on how to use aroma perfume spray. At study termination, complete experimental data were successfully collected from 43 subjects, with 32 randomized to the

treatment group and 11 to the control group. The average age of the subjects was 31.37 ± 5.36 (range 25-50). The two groups had no significant difference in demographics such as age, job title, career status, advanced skills, and educational background.

Since the study recruited volunteers selected randomly from open the community, a baseline average sleep quality score would be necessary as a background control when scoring the treatment group. The background control score on PSQI was 10.5, which is well at the middle between PSQI from 0-21; and the background control score on consumer behavior was 6.

In the report, we presented 2 separate scoring, they were 1) overall integrated score including from PSQI and consumer behavior questionnaires' scores; and 2) different scores on consumer behavior questionnaire.

Overall integrated score, it was integrated scores including PSQI technical score (0-21) and consumer behavior score (0-18).

Control as baseline 10.5 [Attachment B], meant treatment group score ≤ 10.5 , indicated sleep quality improvement.

Consumer behavior score control as 6, meant ≥6, indicated positive consumer behavior feedback to the tested aroma sample.

The analysis of overall integrated score, the treatment group had a significant improvement in sleep quality after aromatherapy as compared to before and background control, the score was 80% (max. 100%). [Attachment C]

The analysis of consumer behavior score, the treatment group had significant positive feedback after aromatherapy as compared to before:

- Fell asleep faster than usual, 88%
- Felt calm and relaxed, 94%

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- Has a peaceful night's sleep, 94%
- Felt more refreshed in the morning, 65%
- Liked the fragrance, 100%
- Would recommend to others, 100%

In conclusion, our study found that aromatherapy (for Every Body) formulation is an effective treatment in improving sleep quality. Our study is quite aligned with the world leading research finding such as publication in Complementary Therapies in Medicine 60 (2021) 102739, on "Effect of aromatherapy on sleep quality of adults and elderly people: A systematic literature review and meta-analysis".

"For Her" Group: Results and **Interpretations**

The study attempted to recruit 50 subjects initially. Only one subject withdrew from the study due to not following the standard instruction properly on how to use aroma perfume spray. At study termination, complete experimental data were successfully collected from 49 subjects, with 32 randomized to the treatment group and 17 to the control group. The average age of the subjects was 29.27 \pm 5.29 (range 25-50). The two groups had no significant difference in demographics such as age, job title, career status, advanced skills, and educational background.

Since the study recruited volunteers were selected randomly from open community, a baseline average sleep quality score would be necessary as a background control when scoring the treatment group. The background control score on PSQI was 10.5, which is well at the middle between PSOI from 0-21 [Attachment B]; and the background control score on consumer behavior was 6.

In the report, we presented 2 separate scoring, they were 1) overall integrated score including from PSQI and consumer behavior questionnaires' scores; and 2) different scores on consumer behavior questionnaire.

Overall integrated score, it was an integrated scores including PSOI technical score (0-21) and consumer behavior score (0-18).

Control as baseline 10.5[Attachment B], meant treatment group score \leq 10.5, indicated sleep quality improvement,

Consumer behavior score

control as 6, meant ≥6, indicated positive consumer behavior feedback to the tested aroma sample.

The analysis of overall integrated score, the treatment group had a significant improvement in sleep quality after aromatherapy as compared to before and background control, the score was 94% (max. 100%). [Attachment C]

The analysis of consumer behavior score, the treatment group had significant positive feedback after aromatherapy as compared to before:

- Fell asleep faster than usual, 94%
- Felt calm and relaxed, 97%
- Has a peaceful night's sleep, 94%
- Felt more refreshed in the morning, 68%
- Liked the fragrance, 100%
- Would recommend to others, 100%

In conclusion, our study found that aromatherapy (for Her) formulation is an effective treatment in improving sleep quality. Our study is quite aligned with the world leading research finding such as publication in Complementary Therapies in Medicine 60 (2021) 102739, on "Effect of aromatherapy on sleep quality of adults and elderly people: A systematic literature review and meta-analysis".

"For Him" Group: Results and Interpretations

The study attempted to recruit 50 subjects initially. Seven subjects withdrew from the study due to not follow properly the standard instruction on how to use aroma perfume spray. At study termination, complete experimental data were successfully collected from 43 subjects, with 28 randomized to the treatment group and 15 to the control group. The average age of the subjects was 36.27 ± 4.59 (range 30-50). The two groups had no significant difference in demographics such as age, job title, career status, advanced skills, and educational background.

Since the study recruited volunteers were selected randomly from open community, a baseline average sleep quality score would be necessary as a background control when scoring the treatment group. The background control score on PSQI was 10.5, which is well at the middle between PSQI from 0-21 [Attachment B]; and the background control score on consumer behavior was 6.

In the report, we presented 2 separate scoring, they were 1) overall integrated score including from PSQI and consumer behavior questionnaires' scores; and 2) different scores on consumer behavior questionnaire.

Overall integrated score, it was an integrated scores including PSQI technical score (0-21) and consumer behavior score (0-18).

Control as baseline 10.5[Attachment B], meant treatment group score \leq 10.5, indicated sleep quality improvement,

Consumer behavior score

control as 6, meant ≥6, indicated positive consumer behavior feedback to the tested aroma sample.

The analysis of overall integrated score, the treatment group had a significant improvement in sleep quality after aromatherapy as compared to before and background control, the score was 90% (max. 100%). [Attachment C]

The analysis of consumer behavior score, the treatment group had significant positive feedback after aromatherapy as compared

- Fell asleep faster than usual, 93%
- · Felt calm and relaxed, 86%
- Has a peaceful night's sleep, 86%
- Felt more refreshed in the morning, 71%
- Liked the fragrance, 93%
- Would recommend to others, 96%

In conclusion, our study found that aromatherapy (for Him) formulation is an effective treatment in improving sleep quality. Our study is quite aligned with the world leading research finding such as publication in Complementary Therapies in Medicine 60 (2021) 102739, on "Effect of aromatherapy on sleep quality of adults and elderly people: A systematic literature review and meta-analysis".

"For Mature" Group: Results and Interpretations

The study attempted to recruit 50 subjects initially. Nine subjects withdrew from the study due to not following the standard instruction properly on how to use aroma perfume spray. At study termination, complete experimental data were successfully collected from 37 subjects, with 27 randomized to the treatment group and 10 to the control group. The average age of the subjects was 66.67 ± 5.25 (aged 60 or above). The two groups had no significant difference in demographics such as age, job title, career status, advanced skills, and educational background.

Since the study recruited volunteers were selected randomly from open community, a baseline average sleep quality score would be necessary as a background control when scoring the treatment group. The background control score on PSQI was 10.5, which is well at the middle between PSOI from 0-21

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[Attachment B]; and the background control score on consumer behavior was 6.

In the report, we presented 2 separate scoring, they were 1) overall integrated score including from PSQI and consumer behavior questionnaires' scores; and 2) different scores on consumer behavior questionnaire.

Overall integrated score, it was an integrated scores including PSQI technical score (0-21) and consumer behavior score (0-18).

Control as baseline 10.5[Attachment B], meant treatment group score ≤ 10.5, indicated sleep quality improvement,

Consumer behavior score

control as 6, meant ≥6, indicated positive consumer behavior feedback to the tested aroma sample.

The analysis of overall integrated score, the treatment group had a significant improvement in sleep quality after aromatherapy as compared to before and background control, the score was 82% (max. 100%). [Attachment C]

The analysis of consumer behavior score, the treatment group had significant positive feedback after aromatherapy as compared

• Felt more refreshed in the morning, 66%

- Fell asleep faster than usual, 82%
- · Felt calm and relaxed, 74%
- Has a peaceful night's sleep, 74%
- Liked the fragrance, 88%
- · Would recommend to others, 82%

In conclusion, our study found that aromatherapy (for Mature) formulation is an effective treatment in improving sleep quality. Our study is quite aligned with the world leading research finding such as publication in Complementary Therapies in Medicine 60 (2021) 102739, on "Effect of aromatherapy on sleep quality of adults and elderly people: A systematic literature review and meta-analysis".

"For Kids" Group: Results and **Interpretations**

The study attempted to recruit 50 subjects initially. Twenty-five subjects withdrew from the study due to not following the standard instruction properly on how to use aroma perfume spray. At study termination, complete experimental data were successfully collected from 25 subjects, with 15 randomized to the treatment group and 10 to the control group. The average age of the subjects was

ATTACHMENT C - Conversion Table - To reflect the degree of sleep Improvement

PSQI (10.5 as control reference, any score below represents having sleep improvement	Integrated Score (in %)
10.5	50
10	55
9.5	60
9.0	65
8.5	67.5
8.0	70
7.5	72.5
7.0	75
6.5	77.5
6.0	80
5.5	82.5
5.0	85
4.5	87.5
4.0	90
3.5	92.5
3.0 (Best score in this study)	95
2.5	96
2.0	97
1.5	98
1.0	99
0.0	100

 11.12 ± 1.38 (ages between 3-month to 12 years old). The two groups had no significant difference in demographics such as age, skills, and educational background.

Since the study recruited volunteers were selected randomly from open community, a baseline average sleep quality score would be necessary as a background control when scoring the treatment group. The background control score on PSQI was 10.5, which is well at the middle between PSQI from 0-21 [Attachment B]; and the background control score on consumer behavior was 6.

In the report, we presented 2 separate scoring, they were 1) overall integrated score including from PSQI and consumer behavior questionnaires' scores; and 2) different scores on consumer behavior questionnaire.

Overall integrated score, it was an integrated scores including PSQI technical score (0-21) and consumer behavior score (0-18). Control as baseline 10.5[Attachment B], meant treatment group score ≤ 10.5 , indicated

Consumer behavior score

sleep quality improvement,

control as 6, meant ≥6, indicated positive consumer behavior feedback to the tested aroma sample.

The analysis of overall integrated score, the treatment group had a significant improvement in sleep quality after aromatherapy as compared to before and background control, the score was 68% (max. 100%). [Attachment C]

The analysis of consumer behavior score, the treatment group had significant positive feedback after aromatherapy as compared to before:

- Fell asleep faster than usual, 73%
- Felt calm and relaxed, 66%
- Has a peaceful night's sleep, 60%
- Felt more refreshed in the morning, 73%
- Liked the fragrance, 66%
- Would recommend to others, 66%

In conclusion, our study found that aromatherapy (for kids) formulation is a mild treatment in improving sleep quality.

For the full research paper please contact: Miracle Plant International Pty Ltd Tel: +61 1300 232 161 Email: catchow@miracleplant.com.au www.miracleplant.com.au

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