ISSN 2456-3110
Vol 9 · Issue 12
December 2024

JAiMS
INTERNATIONAL

Journal of Ayurveda and Integrated Medical Sciences

www.jaims.in

JAIMS

An International Journal for Researches in Ayurveda and Allied Sciences

Maharshi Charaka
Ayurveda

Indexed

Journal of
Ayurveda and Integrated Medical Sciences
ISSN 2456-3110
ORIGINAL ARTICLE December 2024

Combined effect of Lavender Oil and Hot Foot Bath on Migraine Patients: A Randomized Controlled Trial

Suhas B[1], Vineetha AN[2], Nitesh MK[3], Vanitha Shetty[4], Prajwal HM[5]

[1]*Post Graduate Scholar, Department of Clinical Naturopathy, Alvas College of Naturopathy and Yogic Sciences, Mijar, Moodubidire, Mangalore, DK, Karnataka, India.*

[2,3]*Associate Professor, Department of Clinical Naturopathy, Alvas College of Naturopathy and Yogic Sciences, Mijar, Moodubidire, Mangalore, DK, Karnataka, India.*

[4]*Principal, Head Department of Clinical Naturopathy, Alvas College of Naturopathy and Yogic Sciences, Mijar, Moodubidire, Mangalore, DK, Karnataka, India.*

[5]*Assistant Professor, Department of Clinical Naturopathy, Alvas College of Naturopathy and Yogic Sciences, Mijar, Moodubidire, Mangalore, DK, Karnataka, India.*

ABSTRACT

Introduction: Migraine headaches, marked by recurrent, moderate-to-severe unilateral pain, present a significant health burden. This study evaluates the effectiveness of lavender oil inhalation combined with hot foot baths in managing pain, disability, and quality of life among individuals with migraine. **Materials and Methods:** A randomized controlled trial was conducted with 70 participants aged 18–44, screened and allocated into intervention and control groups. The intervention included lavender oil inhalation for 5 minutes and hot foot baths for 20 minutes daily over 15 days. **Results:** Pre - and post - assessment data were analysed using tools such as the Visual Analog Scale (VAS), Headache Disability Index (HDI), Pain Disability Index (PDI), Migraine Specific Quality of Life (MSQOL), and the Migraine Disability Assessment Scale (MIDAS). Results indicated significant improvement in the intervention group across all metrics ($p \leq 0.05$). The control group showed limited improvement, attributed to analgesic use during severe attacks. **Discussion:** These findings suggest that combined lavender oil and hot foot bath therapy is a viable complementary approach for migraine management, promoting pain relief, reduced disability, and enhanced quality of life.

Key words: *Complementary and alternative medicine (CAM), headache disability index (HDI), lavender oil, migraine, pain disability index (PDI).*

INTRODUCTION

Migraine is a complex, recurrent headache disorder affecting approximately 12% of the global population, with a higher prevalence among women.[1] pg 800 It typically presents as a unilateral, pulsating pain accompanied by symptoms such as nausea, photophobia, and phonophobia, significantly impairing daily activities and reducing the quality of life.[2] The burden of migraine is not only physical but also economic, as it affects productivity and leads to increased healthcare costs.[3] Despite its prevalence and impact, treatment options are often limited or come with undesirable side effects, as many migraine therapies rely on pharmaceutical agents such as non-steroidal anti-inflammatory drugs (NSAIDs), triptans, and other medications, which may lead to dependency or adverse reactions over time.[4]

Complementary and alternative medicine (CAM) has emerged as a promising field in the management of chronic conditions like migraine, offering potential solutions that are less invasive and better tolerated.[5] Among CAM therapies, aromatherapy and hydrotherapy have shown efficacy in alleviating pain and improving well-being.[6] Lavender oil, known for its analgesic and anti-inflammatory properties, has been

Address for correspondence:
Dr. Suhas B
Post Graduate Scholar, Department of Clinical Naturopathy, Alvas College of Naturopathy and Yogic Sciences, Mijar, Moodubidire, Mangalore, DK, Karnataka, India.
E-mail: drsuhasb1997@gmail.com

Submission Date: 13/11/2024 Accepted Date: 25/12/2024

Access this article online	
Quick Response Code	Website: www.jaims.in
	DOI: 10.21760/jaims.9.12.6

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used in aromatherapy for centuries, showing particular promise in reducing headache intensity and promoting relaxation.[7] Similarly, hot foot baths (HFB) are employed in hydrotherapy to redirect blood flow and alleviate cerebral congestion, which can relieve headache symptoms.[8]

While both lavender oil and HFB have individually demonstrated benefits in headache management, there is limited research on their combined effect on migraine. This study aims to investigate the efficacy of combining lavender oil aromatherapy and hot foot baths in reducing pain intensity, disability, and improving the quality of life in migraine patients, thereby contributing to an evidence-based approach in CAM for headache management.

Aim and Objectives

Primary Objective

- To evaluate the combined effect of lavender oil aromatherapy and hot foot bath (HFB) on pain intensity in migraine patients.

Secondary Objectives

- To assess the impact of this combined intervention on migraine-related disability and quality of life.
- To determine the feasibility of lavender oil and HFB as an alternative therapy for migraine symptom management.

Materials and Methods

Ninety subjects with headache were initially evaluated, and 70 participants aged 18– 44 years were selected based on routine medical examination and fulfillment of any 4 diagnostic criteria and inclusion criteria for Migraine Headache were recruited for study. Using simple randomization-Coin toss method, they were divided into two groups. Pre assessments were performed before the intervention, followed by a 15-days intervention consisting of 5 minutes of lavender oil sniffing in comfortable sitting position before 1hour or after 2 hours of food given in the morning and 20 minutes of hot foot bath in the evening were given for 15 consecutive days. (9) Follow-up was done & post assessments were performed at the last day after the treatment. Institutional ethical committee approval was obtained and Participants received comprehensive study information and provided informed consent.

Description of subjects including the selection of sample from the population

The subjects will be recruited from the Alva's Naturopathy Outpatient department in and around Moodbidri, Managed by Alva's education foundation, Moodbidri-574227, Dakshina Kannada district, Karnataka, India.

Ethical Considerations

Eligible participants received an information sheet detailing the nature of the study and the proposed intervention. They were given sufficient of time to verify this study details given in information sheet. They then had the opportunity to seek clarification by asking questions. Only those who agreed to participate were asked to sign an informed consent form indicating their willingness. The study received approval from the Institutional Ethics Committee (ACNYS/IECHS/2022/70).

CTRI Registration number - CTRI/2023/11/059902.

Inclusion criteria

- Age: 18 to 44 years,
- Gender: Both male and female subjects
- At least 5 headache attacks that 4-72 hours, with characteristics of unilateral location.
- Subjects who are scoring between 6- 20 points (mild to moderate stage) / grading between grade 2 to grade 3 in MIDAS Questionnaire
- Subjects those who are willing to participate in the study

Table 1: Diagnostic Criteria for Migraine Headache:

Headache feature	Migraine headache
Pain location	unilateral
Pain quality	Pulsative or throbbing feature
Pain intensity	Mild /moderate

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Effect on activities	aggravation by or causing avoidance of routine physical activity (e.g., walking or climbing stairs)
Other symptoms	nausea and/or vomiting photophobia and phonophobia
Duration of headache	4-72 hours
Frequency of headache	15 or more days per month for a period of more than 3 months – chronic migraine
	At least 8 days per month 14 or fewer headache days per month

Any 4 of the above-mentioned criteria will be considered for the recruitment.[10]

Exclusion criteria

- Subjects with additional tension headache
- Subjects with use of any allopathic medications and other system of medicine
- Subjects with other neurological disorders.
- Weak and systemic illness subjects.
- Both the gender less than 18 years and more than 44 years.

Study design - A randomized control trial

Study sample size: n = 70

Grouping: Participants are randomly assigned to two groups using simple randomization - Coin toss method

a) Study group (n = 35)

b) Control group (n = 35)

Study period: 15 days

Intervention

Intervention for study group (n=35)

Intervention will be given in between 7 am to 3 pm. (11) Patients will be asked to sit comfortably on a chair and immerse their legs in water at a temperature of 102°F-104°F that is increased gradually and the water is raised to the level of the calf muscle. Then subjects will be asked to sniff a piece of cotton wool which contains 5 drops of lavender essential oil, at a distance of 5cm from the nose with deep inhalations for 5 minutes only, during beginning of the intervention. A maximum temperature of 115°F - 122°F is reached during the last 2-3 minutes. The duration of the treatment will be 20 min. (12)(13)

Control Group will be under Standard Medical Protocol

Figure 1: Illustration of study plan

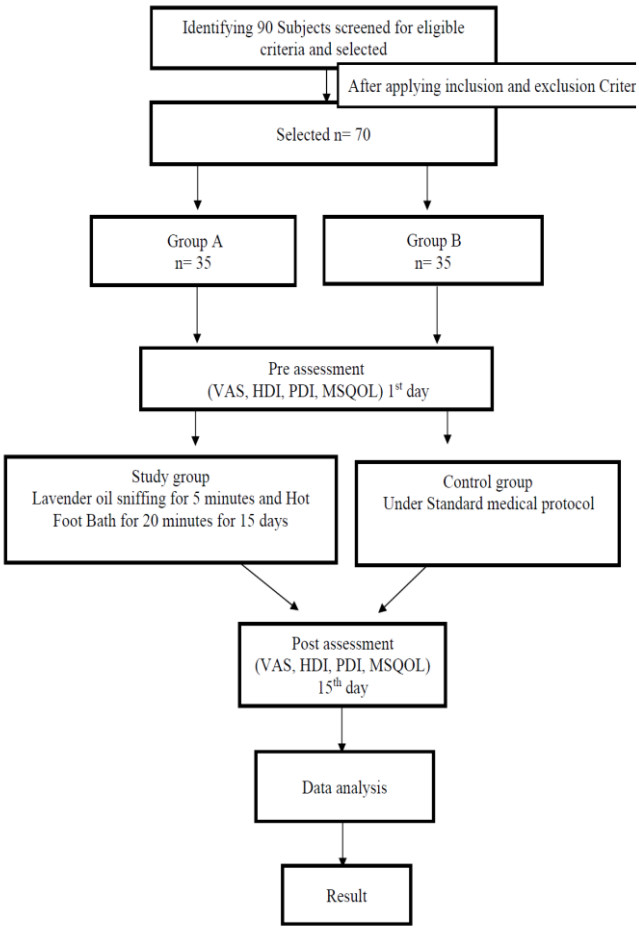

Figure 2: Hot foot bath procedure

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Hot foot bath: Temperature: 40°C-45°C (104°F -113°F)

Duration: 20 minutes.

Phase 1: Preparatory stage:

Subjects were asked to relax with minimal dress where their leg is exposed up to calf region in hot water.

Phase 2: Operative phase:

Small tub containing hot water of temperature 40°C - 45°C (104°F - 113°F) will be given where the subject has to immerse the legs up to the calf muscle in water and the patient is covered with a blanket to prevent the heat loss for the duration of 20min.[14]

Temperature of water was monitored using SYGA digital thermometer with fork throughout the procedure.

Phase 3: Post-Operative phase:

- The foot was dried by lightly rubbing them with a dry cloth.
- Participants were advised to avoid sudden exposure to cold or stressful activity immediately after treatment.

Assessments

Pain Disability Index

The Pain Disability Questionnaire (PDQ) is designed to assess disability by evaluating the interplay of biopsychosocial factors in the development of pain and disability. It measures both physical and psychosocial aspects, each scored separately. Participants rate their level of disability across 15 daily living activities on a scale from 0 (no disability) to 10 (complete disruption). Scores are categorized as mild/moderate (0–70), difficult (71–100), and extreme (101–150).[15]

Headache disability index (HDI):

The 25-item Headache Disability Inventory (HDI) was developed to quantitatively evaluate the impact of headaches on daily life. Each item is scored as "yes" (4 points), "sometimes" (2 points), or "no" (0 points), based on empirical medical data. Total scores range as follows: 10–28 indicates mild impairment, 30–48 moderate impairment, 50–68 severe impairment, and 72 or more signifies total disability.[16]

Visual Analogue Scale (VAS):

The Visual Analogue Scale (VAS) is a reliable tool for measuring pain intensity. It features a 100 mm straight line with endpoints representing "no pain at all" and "as bad as it can be." Participants mark their pain level on the line, and the distance from the starting point indicates their pain score on a scale of 0 to 100.[17]

Migraine Specific Quality of Life (MSQOL) Questionnaire:

The Migraine Specific Quality of Life Questionnaire (MSQOL) was developed based on clinical observations and literature reviews, highlighting a gap between the quality-of-life concerns of individuals with migraines and the areas assessed by existing tools. Quality of life is defined as subjective well-being.[18]

Data extraction and Analysis

Data extraction

The data was collected using three outcome variables. The assessments were collected on the first day (baseline data) and the end of 15 days (post data). The data was organized in Microsoft Excel sheets (version 2021)

Data Analysis

The data was visually inspected for manual typographic errors. The Wilcoxon signed rank test for Normality showed that the data was normally distributed. Paired samples t-test was used to assess within group differences. ANCOVA was performed to assess between group changes controlled for their respective baseline values. Levene's test for equality of variances were performed.

OBSERVATIONS AND RESULTS

A total of 70 participants completed the study, with 35 in the intervention group (lavender oil and HFB) and 35 in the control group. The observations are summarized below, with results presented in Tables 1-3.

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Table 2: Baseline Characteristics

Both groups were comparable in terms of age, gender, and baseline scores for pain intensity, disability, and quality of life measures.

Characteristic	Intervention Group (n=35)	Control Group (n=35)
Mean Age (years)	29.4 ± 5.8	30.1 ± 6.3
Gender (M/F)	14/21	15/20
Baseline VAS Score	7.5 ± 1.2	7.4 ± 1.3
Baseline HDI Score	60.2 ± 9.3	59.7 ± 8.9
Baseline PDI Score	55.8 ± 10.1	56.2 ± 9.8
Baseline MSQOL Score	45.5 ± 7.5	45.8 ± 7.7

Table 3: Pre-and post-Intervention Scores

Significant reductions in pain intensity (VAS), headache disability (HDI), and pain disability (PDI), along with improvements in quality of life (MSQOL), were observed in the intervention group.

Outcome Measure	Intervention Group Pre (Mean ± SD)	Intervention Group Post (Mean ± SD)	Control Group Pre (Mean ± SD)	Control Group Post (Mean ± SD)
VAS Score	7.5 ± 1.2	3.2 ± 1.1	7.4 ± 1.3	7.1 ± 1.4
HDI Score	60.2 ± 9.3	30.4 ± 8.7	59.7 ± 8.9	58.9 ± 8.5
PDI Score	55.8 ± 10.1	28.6 ± 9.2	56.2 ± 9.8	55.5 ± 9.3
MSQOL Score	45.5 ± 7.5	75.1 ± 6.8	45.8 ± 7.7	46.2 ± 7.5

Statistical Analysis

- **VAS Score:** Significant reduction in pain intensity was found in the intervention group ($p \leq 0.05$) with no significant change in the control group.
- **HDI and PDI Scores:** The intervention group showed a significant reduction in disability ($p \leq 0.05$) compared to the control group.
- **MSQOL Score:** Quality of life significantly improved in the intervention group ($p \leq 0.05$), while no significant change was observed in the control group.

Table 4: Between-Group Comparison of Outcome Measures

This table compares the post-intervention scores of the intervention group (lavender oil and HFB) with the control group, showing statistically significant improvements in the intervention group across all outcome measures.

Outcome Measure	Intervention Group Post (Mean ± SD)	Control Group Post (Mean ± SD)	p-value
VAS Score	3.2 ± 1.1	7.1 ± 1.4	≤ 0.05
HDI Score	30.4 ± 8.7	58.9 ± 8.5	≤ 0.05
PDI Score	28.6 ± 9.2	55.5 ± 9.3	≤ 0.05
MSQOL Score	75.1 ± 6.8	46.2 ± 7.5	≤ 0.05

Interpretation

- **VAS Score:** Pain intensity significantly decreased in the intervention group compared to the control group.
- **HDI Score:** Headache-related disability was significantly lower in the intervention group.
- **PDI Score:** Pain-related disability showed a significant reduction in the intervention group.
- **MSQOL Score:** Quality of life significantly improved in the intervention group compared to controls.

These results indicate that the combined use of lavender oil and HFB significantly reduces pain intensity, headache-related disability, and improves quality of life in migraine patients compared to routine care alone.

Discussion

The present study investigated the combined effects of lavender oil sniffing and hot foot baths as complementary treatments for migraine headaches.[19]

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Over 15 days, participants who underwent these interventions demonstrated significant improvement across multiple parameters, including VAS, HDI, PDI, MIDAS, and MSQOL-R,[20] with a statistically significant difference ($p \leq 0.05$) compared to the control group.[21] These findings suggest that this dual-therapy approach may provide a comprehensive and effective strategy for managing migraines.[22]

Lavender oil, with its anxiolytic, anti-inflammatory, and vasodilatory properties, targets central and peripheral nociceptive pathways involved in migraine pathophysiology.[23,24] Its ability to modulate neurotransmitter systems, such as GABA and serotonin, and reduce neurogenic inflammation offers significant therapeutic potential for migraine relief.[25,26] Hot foot baths complement these effects by improving peripheral circulation, promoting parasympathetic nervous system activity, and alleviating stress-induced migraine triggers.[27,28] Together, these therapies target both the root causes and symptoms of migraines, providing a holistic treatment approach.

The observed reduction in pain and disability among participants highlights the value of combining these two complementary therapies.[29] The absence of adverse effects and the economic feasibility of the interventions further underscore their practicality for wider clinical application. This study also aligns with previous findings suggesting that complementary and alternative medicine (CAM) therapies, including hydrotherapy and aromatherapy, hold promise for improving the quality of life for migraine sufferers.[30]

However, some reductions in the control group may be attributed to the consumption of analgesics during severe attacks. This underscores the need for studies that better isolate the effects of the interventions. Additionally, while both lavender oil and hot foot baths are individually effective, their combined use appears to enhance outcomes by addressing multiple aspects of migraine pathophysiology.

Strengths

The study's strengths include a high retention rate, with no participants withdrawing, and the absence of side effects. The interventions are simple, cost-effective, and accessible, making them suitable for implementation in both clinical and home settings.

Limitations

Despite these promising findings, the study is limited by its small sample size and reliance on subjective outcome measures, which may introduce bias. A shorter follow-up period compared to other studies may have also constrained the observed benefits, particularly regarding long-term outcomes.

Future Directions

Future research should aim to address these limitations by incorporating larger sample sizes, longer follow-up periods, and the inclusion of objective biomarkers to validate outcomes. Comparative studies examining the efficacy of this dual-therapy approach against standard pharmacological treatments would further strengthen the evidence base. Exploring the effects of varying intervention durations and intensities may also provide insights into optimizing treatment protocols.

In conclusion, the combination of lavender oil sniffing and hot foot baths offers a promising, non-invasive, and cost-effective approach for managing migraines. This study serves as a foundation for further exploration into integrated, CAM-based strategies for migraine treatment, with the potential to significantly improve patients' quality of life.

CONCLUSION

This study highlights the effectiveness of combining lavender oil aromatherapy and hot foot bath (HFB) as a complementary therapy for managing migraines. The major findings indicate that this intervention significantly reduces pain intensity, headache-related disability, and improves the quality of life in migraine patients. These results are particularly relevant in light of the limitations and side effects associated with conventional migraine treatments, offering patients an alternative that is both natural and non-invasive.

The relevance of this combined approach lies in its accessibility, affordability, and ease of application,

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making it a practical option for individuals seeking alternative or supplementary treatments for migraine relief. The study underscores the potential of complementary and alternative medicine (CAM) therapies, especially for those who prefer non-pharmacological approaches or are sensitive to conventional medications.

Further research could build on these findings by exploring long-term effects, varying dosages, and combining lavender oil and HFB with other CAM therapies. Additionally, studies assessing individual differences in response to aromatherapy may help tailor treatment for more personalized care. Ultimately, this study contributes valuable insights into CAM options for migraine, offering a promising, patient-centered approach to improving migraine management and quality of life.

Acknowledgement

I would like to express my sincere gratitude to **Dr Ragavendra Samy Balakrishnan** for his invaluable contributions as a statistician in Analyzing the research data and providing insightful interpretations of the results. His expertise and guidance have been instrumental in shaping the outcomes of this study.

I also extend my heartfelt thanks to **Alva's College of Naturopathy & Yogic Sciences** for their unwavering support and resources throughout the course of this research. Their encouragement and facilities played a vital role in enabling this study to reach its completion.

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How to cite this article: Suhas B, Vineetha AN, Nitesh MK, Vanitha Shetty, Prajwal HM. Combined effect of Lavender Oil and Hot Foot Bath on Migraine Patients: A Randomized Controlled Trial. J Ayurveda Integr Med Sci 2024;12:50-57.
http://dx.doi.org/10.21760/jaims.9.12.6

Source of Support: Nil, **Conflict of Interest:** None declared.

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