International Journal of Public Health and Medical Research
ISSN: 3006-7707 (Print), ISSN: 3006-3752 (Online) | Volume 6, Number 4, Year 2026
DOI: https://doi.org/10.62051/ijphmr.v6n4.17
Journal homepage: https://wepub.org/index.php/IJPHMR/index

Lavender Essential Oil as Treatment for Chronic Migraine: A Protocol for Non-Inferiority Randomized Controlled Trial

Xiaocong Wang

School of Public Health and Preventive Medicine, Monash University, Melbourne, Australia

ABSTRACT

This study is a randomized, investigator-blinded, controlled phase III clinical trial designed to compare the efficacy of daily atomized inhalation of lavender essential oil versus 50 mg sumatriptan tablets among Australians aged 18–65 years with chronic migraine, with a 3-month follow-up period. The primary outcome is the monthly reduction in headache days, defined as an improvement from moderate or severe pain to mild or no pain. Eligible participants diagnosed with chronic migraine by general practitioners and providing informed consent are randomized 1:1 to the intervention group (lavender essential oil) or the control group (sumatriptan tablets). This protocol aims to evaluate whether lavender essential oil is non-inferior to standard pharmaceutical treatment for chronic migraine management.

KEYWORDS

Chronic migraine; Lavender essential oil; Aromatherapy; Non-inferiority trial; Randomized controlled trial; Sumatriptan; Headache management

1. INTRODUCTION

Migraine is a neurogenic primary headache disorder classified as either episodic or chronic [1]. As a major global public health issue, migraine affects more than 4.9 million Australians [2]. Migraine pain often begins unilaterally and may spread bilaterally as severity increases [3]. Chronic migraine is associated with a higher disability rate than episodic migraine [4], and is defined as headache occurrence on at least 15 days per month [5]. Common symptoms include photophobia, phonophobia, nausea, vomiting, and other gastrointestinal reactions, which severely impair work, social activities, and quality of life [5].

Current pharmacotherapies are mostly developed for episodic migraine, with limited options optimized for chronic forms [6]. Triptans are first-line clinical treatments [7], and sumatriptan is a representative agent with a rapid elimination half-life of approximately 2.5 hours [8]. However, long-term use carries risks of adverse effects and medication overuse, creating a need for safer complementary therapies [5]. Aromatherapy has gained attention as an alternative intervention, and lavender essential oil has shown analgesic, sedative, and anxiolytic effects in multiple studies [9–14]. Its active components, linalool and linalyl acetate, contribute to neurological modulation and pain relief [12]. This trial aims to fill the evidence gap by evaluating the non-inferiority of atomized lavender essential oil for chronic migraine.

2. HYPOTHESIS

2.1. Null Hypothesis

Daily atomized inhalation of lavender essential oil is inferior to 50 mg/day sumatriptan tablets in patients with chronic migraine.

2.2. Alternative Hypothesis

Daily atomized inhalation of lavender essential oil is non-inferior to 50 mg/day sumatriptan tablets in Australian adults with chronic migraine.

3. AIMS

This clinical trial aims to evaluate the effectiveness of atomized lavender essential oil in reducing migraine headache severity and frequency among adults with chronic migraine over a 3-month follow-up period.

4. STUDY DESIGN

This is a non-inferiority, randomized, investigator-blinded, controlled phase III trial comparing daily atomized inhalation of lavender essential oil with oral sumatriptan tablets in Australians aged 18–65 years, with a 3-month follow-up. Eligible participants are randomized at a 1:1 allocation ratio. Written informed consent is obtained from all participants. This protocol is designed in accordance with the SPIRIT 2013 statement [15].

5. STUDY POPULATION

5.1. Inclusion Criteria

Age between 18 and 65 years

Clinically diagnosed chronic migraine

Voluntary participation and signed informed consent

No use of analgesics or aromatherapy in the past 3 months

Normal olfactory function

Ability to complete the 3-month follow-up

5.2. Exclusion Criteria

Other primary headaches (cluster headache, tension-type headache, medication-overuse headache)

Allergy to lavender essential oil or triptans

Severe comorbidities (cardiovascular disease, liver disease, acute infection, stroke)

Participation in other clinical trials

Pregnancy, lactation, or inadequate contraception

Inability to comply with study procedures

6. RECRUITMENT AND RETENTION

6.1. Recruitment Process

Participants are recruited from the Melbourne Headache Centre via invitation letters and informational posters. Research staff screen potential participants using the centre's database based on inclusion and exclusion criteria. Eligible participants are assigned a unique ID and randomized 1:1 to the intervention or control group using a central computer system.

6.2. Informed Consent and Retention Strategies

Research staff fully explain the study purpose, intervention procedures, risks, and benefits, and obtain written informed consent. Retention strategies include:

Weekly SMS reminders

Free aromatherapy workshops

Study product gifts for compliant participants

Clear communication and prompt responses to questions

7. INTERVENTION AND COMPARATOR

7.1. Intervention Group

Participants inhale 6–8 drops (0.2–0.3 mL) of Australian In Essence lavender essential oil mixed with 100 mL water in a 360° diffuser for 20 minutes at headache onset, seated 30 cm from the device. Headache severity is recorded every 30 minutes for 2 hours.

7.2. Control Group

Participants take oral sumatriptan (Imigran) 50 mg at headache onset. Headache severity is monitored using the same schedule as the intervention group [16].

7.3. Randomization and Blinding

Block randomization (4 participants per block) is used to generate a concealed allocation sequence. Researchers are blinded to group assignments; participants receive sealed envelopes indicating their group [17].

8. OUTCOME MEASURES

8.1. Primary Outcome

Monthly reduction in headache days, defined as improvement from moderate/severe pain to mild/no pain measured by the Visual Analogue Scale (VAS): 0 = no pain, 1–3 = mild, 4–6 = moderate, 7–9 = severe [18].

8.2. Secondary Outcomes

Change in VAS scores from baseline to final assessment

Monthly frequency of adverse events (AEs)

9. SAMPLE SIZE AND STATISTICAL ANALYSIS

9.1. Sample Size

A total of 40 participants (20 per group) are required, based on an effect size of 0.95, one-sided $\alpha = 0.05$, and 10% dropout rate [19].

9.2. Statistical Methods

Intention-to-treat (ITT) analysis is applied. Independent two-sample t-tests are used to compare primary and secondary outcomes. $P < 0.05$ is considered statistically significant.

10. ADVERSE EVENTS

All adverse events are self-reported by participants and reviewed monthly by the Data and Safety Monitoring Board (DSMB). Serious adverse events are reported immediately to the ethics committee.

11. ETHICAL AND REGULATORY CONSIDERATIONS

This trial follows the Declaration of Helsinki, Good Clinical Practice (GCP), and Australian national ethical guidelines. Ethics approval is obtained prior to recruitment. Participants may withdraw at any time without penalty, and all personal data are kept confidential.

12. DATA MANAGEMENT

Data are collected in case report forms (CRFs) and double-entered into Excel by two independent researchers. A data manager verifies accuracy and resolves discrepancies. All documents are stored in locked cabinets and password-protected databases.

13. CONCLUSION

This randomized controlled trial evaluates whether atomized lavender essential oil is non-inferior to oral sumatriptan for chronic migraine. Positive results will support lavender aromatherapy as a safe, low-cost complementary therapy, reducing reliance on conventional medications and improving patient quality of life.

REFERENCES

[1] K.R. Peck, Y.L. Johnson, T.A. Smitherman: Migraine. Handbook of Clinical Neurology, (2016), p.283–293.

[2] D.A. Economics: Migraine in Australia Whitepaper (Deloitte Access Economics Report, Australia 2018)

[3] ICHD-II Classification: Parts 1–3: Primary, Secondary and Other. Cephalalgia, Vol. 24 (2004) No.1_suppl, p.23–136.

[4] M.E. Bigal, D. Serrano, M. Reed, R.B. Lipton: Chronic migraine in the population: burden, diagnosis, and satisfaction with treatment. Neurology, Vol. 71 (2008) No.8, p.559–566.

[5] M.W. Weatherall: The diagnosis and treatment of chronic migraine. Therapeutic Advances in Chronic Disease, Vol. 6 (2015) No.3, p.115–123.

[6] T.J. Schwedt: Chronic migraine. BMJ, Vol. 348 (2014)

[7] S.D. Silberstein: Report of the Quality Standards Subcommittee of the American Academy of Neurology.

[8] M.J. Brown, P. Sharma, P.N. Bennett: Clinical Pharmacology (Elsevier, UK 2012).

[9] A. Olapour, K. Behaeen, R. Akhondzadeh: The effect of inhalation of aromatherapy blend containing lavender essential oil on cesarean postoperative pain. Anesthesiology and Pain Medicine, Vol. 3 (2013) No.1, p.203.

[10] Y.B. Yip, S.H. Tse: The effectiveness of relaxation acupoint stimulation and acupressure with aromatic lavender essential oil for non-specific low back pain. Complementary Therapies in Medicine, Vol. 12 (2004) No.1, p.28–37.

[11] R. Soltani, S. Soheilipour, V. Hajhashemi: Evaluation of the effect of aromatherapy with lavender essential oil on post-tonsillectomy pain in pediatric patients. International Journal of Pediatric Otorhinolaryngology, Vol. 77 (2013) No.9, p.1579–1581.

[12] S.H. Huang, L. Fang, S.H. Fang: The effectiveness of aromatherapy with lavender essential oil in relieving post arthroscopy pain. JMED Research, Vol. 2014 (2014), p.1–6.

[13] H.M. Cavanagh, J.M. Wilkinson: Lavender essential oil: a review. Australian Infection Control, Vol. 10 (2005) No.1, p.35–37

[14] L.W. Chien, S.L. Cheng, C.F. Liu: The effect of lavender aromatherapy on autonomic nervous system in midlife women with insomnia. Evidence-Based Complementary and Alternative Medicine, Vol. 2012 (2012)

[15] A.W. Chan, J.M. Tetzlaff, P.C. Gøtzsche: SPIRIT 2013 explanation and elaboration: guidance for protocols of clinical trials. BMJ, Vol. 346 (2013).

[16] NPS MedicineWise: Imigran tablets, https://www.nps.org.au/medicine-finder/imigran-tablets (2021)

[17] J.M. Lachin, J.P. Matts, L.J. Wei: Randomization in clinical trials: Conclusions and recommendations. Controlled Clinical Trials, Vol. 9 (1988) No.4, p.365–374.

[18] B. Aicher, H. Peil, B. Peil: Pain measurement: Visual Analogue Scale (VAS) and Verbal Rating Scale (VRS) in clinical trials with OTC analgesics in headache. Cephalalgia, Vol. 32 (2012) No.3, p.185–197

[19] P. Sasannejad, M. Saeedi, A. Shoeibi: Lavender essential oil in the treatment of migraine headache: a placebo-controlled clinical trial. European Neurology, Vol. 67 (2012) No.5, p.288–291.