Research Protocol

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Ayurveda Section

Comparative Evaluation of *Bala Taila Nasya* and *Pippalyadi Taila Nasya* in the Management of Tension Type Headache (*Vataja Shirashoola*): A Randomised Controlled Trial Protocol

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ABSTRACT

Introduction: Tension Type Headache (TTH) is the most common primary headache disorder, impacting daily life, productivity, and mental health significantly. Traditional treatments like Non-Steroidal Anti-Inflammatory Medication (NSAIDs), muscle relaxants, and antidepressants provide symptomatic relief but are plagued with side-effects like gastric ulcers, Medication-Overuse Headaches (MOH), and dependence. *Vataja Shirashoola*, a TTH in Ayurveda, results from the derangement of *Vata Dosha*. *Nasya* therapy, the intra-nasal application of medicated oils, is a traditional Ayurvedic therapy popularly known to act directly on the central nervous system, enhancing circulation and analgesia. *Bala Taila* and *Pippalyadi Taila* are two Nasya oils that possess neuroprotective and analgesic properties, yet no clinical trials have evaluated their relative or comparative efficacy.

Need of the study: TTH, which is frequently associated with Vataja Shirashoola, is prevalent across the world, but fewer trials are comparing Nasya therapies in its management. Although Bala Taila have been evaluated separately, but its comparison with Pippalyadi taila has not been carried out. Objective measures such as pain scales and quality-of-life questionnaires were also absent in earlier studies. This study attempts to bridge this deficiency through a Randomised Controlled Trial (RCT) incorporating standardised clinical outcomes.

Aim: To evaluate the efficacy of *Bala Taila Nasya* and *Pippalyadi Taila Nasya* in the management of *Vataja Shirashoola* (TTH) in terms of pain reduction, improvement in mobility of the neck, and Quality of Life (QoL).

Materials and Methods: The present study will be randomised controlled trial (RCT) will be conducted in the Pancha*karma* Department, Mahatma Gandhi Ayurveda College, from January 2024 to December 2025. Sixty patients aged 18-60 years with a diagnosis of TTH (*Vataja Shirashoola*) will be divided randomly into two groups: Group P will be administered *Bala Taila Nasya*, and Group Q will be administered *Pippalyadi Taila Nasya*, eight drops in each nostril daily for seven days. The study is of a parallel-group, open-label type. Numerical Rating Scale (NRS), cervical ROM, and a QoL questionnaire will be assessed assessed on days 0, 8, and 16. Demographic information such as age, sex, duration of headache, and lifestyle will be recorded. Statistical analysis will be performed using Statistical Package for the Social Sciences (SPSS) version 26.0 with paired t-tests, Analysis of Variance (ANOVA), and Chi-square tests. A p-value <0.05 will be taken to be statistically significant.

Keywords: Ayurvedic medicine, Intranasal drug delivery, Pain management, Quality of life

INTRODUCTION

Headache disorders are among the most prevalent neurological disorders, significantly affecting an individual's daily functioning and productivity. TTH is the most prevalent, characterised by bilateral, squeezing, or tightening pain, commonly associated with stress, muscle tension, and bad posture [1]. Headache disorders, such as TTH, are among the leading 10 causes of disability, as reported by the Global Burden of Disease (GBD) 2019 study. Epidemiological surveys have shown that approximately 40% of the total population is affected by TTH annually, with a lifetime prevalence of 30-78% [2].

Contemporary medicine, in most instances, manages TTH with symptomatic NSAIDs, muscle relaxants, and antidepressants, whose adverse effects include gastric ulcers, renal failure, and MOH [3]. Chronic NSAID therapy has further been associated with higher cardiovascular disorders and hepatotoxicity risks. Therefore, effective treatments without adverse effects are needed, and they can be used to effectively manage TTH without causing damage to the environment [4].

In Ayurveda (science of life), TTH is practically synonymous with *Vataja Shirashoola* (neurological headache due to the predominance of *Vata Dosha). Vata Dosha* (the governing factor of movement and nervous system functions) is a significant cause of constriction, dryness, and nervous system instability, leading to chronic headaches [5]. *Nasya* therapy (intranasal administration of medicated oil) is one of the most potent treatments described in Ayurvedic literature for head disorders since it has a direct action on the nervous system. The dictum "*Nasa Hi Shiraso Dwaram*" (the nose is the brain's gate) reflects the potential of *Nasya* therapy to deliver therapeutic agents to the central nervous system [6].

Nasya therapy has been practised extensively in Ayurveda for managing neurological disorders as it eliminates vitiated *Doshas* (bioenergetic disturbances) from the cranial cavity [7]. Recent studies validate intranasal drug delivery to target the trigeminal nerve, Cerebrospinal Fluid (CSF), and Blood-Brain Barrier (BBB), achieving rapid pain relief and neuroprotection. Clinical trials show that medicated nasal oils increase cerebral perfusion, reduce neuroinflammation, and modulate pain pathways, thus establishing *Nasya* as an effective management for headaches [8].

Of the Ayurvedic medications used in *Nasya* treatment, *Bala Taila is* widely used in treating *Vataja Shirashoola* due to their anti-inflammatory, analgesic, and neuroprotective effects [9].

Bala Taila has been chosen as the control group in this research due to its effectiveness in neurological disorders, headache relief, and *Vata*-pacifying action. It is also commonly practised clinically due to its neuroprotective and rejuvenating properties, hence being a standard treatment to compare. It has also been commonly practised in *Nasya* therapy to enhance cerebral circulation, ease muscular stiffness, and treat chronic headaches [10].

Pippalyadi Taila, however, is a less researched but promising medication that contains *Pippali* (*Piper longum*) and *Saindhava Lavana* and maximises pain relief, anti-inflammatory action, and tissue penetration. This comparative trial will ascertain whether *Pippalyadi Taila* is as therapeutically efficacious as the already established *Bala Taila Nasya* [11].

Bala Taila: *Bala* (*Sida cordifolia*) is the key herb of *Bala Taila*, which has rejuvenating and nervine tonic activity. It is a nerve tonic that drives away stiffness and promotes circulation to the neck and head area. *Bala Taila* is traditionally employed in Ayurveda in the management of *Vata* aggravation diseases like cervical spondylosis, neuropathy, and chronic headache [12].

Pippalyadi Taila: This preparation, as described in ancient literature such as *Brihad Nighantu Ratnakara*, is an admixture of *Pippali* (*Piper longum*), *Saindhava Lavana* (rock salt), and *Tila Taila* (sesame oil). *Pippali* has decisive analgesic, anti-inflammatory, and neuroprotective actions and helps treat migraines and TTH. *Pippali* with *Saindhava Lavana* facilitates its absorption and action in relieving headaches due to *Vata* imbalance [13].

Scientific studies on intranasal administration of drugs indicate that *Nasya* therapy influences neurological pathways through trigeminal nerve stimulation, which is central to headache pathophysiology [14] enabling penetration of medicated oil in the olfactory region, bypassing the BBB for central nervous system activity. Augmenting cerebral blood flow, inhibiting inflammation, and modulating pain receptor activity. Therefore, *Nasya* can act as a secure, non surgical, and effective alternative to manage chronic headaches, particularly among patients with side-effects from prolonged allopathic drug intake [15].

Most studies have used single *Nasya* preparations alone, without comparative *Bala Taila and Pippalyadi Taila* trials [16]. The previous studies have only focused on subjective relief of symptoms, without objective measurement of pain relief, functional improvement, and QoL. The duration of previous trials has been short, without considering recurrence rates and long-term efficacy. More evidence is needed to include Ayurvedic interventions in conventional headache management protocols. This study will cover these shortcomings by conducting a RCT with quantitative and qualitative outcome measures to allow a scientifically proven comparison of the two *Nasya* preparations.

The TTH is a global health disorder that affects an individual's personal, occupational, and social wellbeing. The conventional treatments provide relief but are addictive and cause side-effects. *Ayurveda* introduces *Nasya* therapy as a natural treatment that works at the root level by correcting *Vata Dosha* balance, improving blood flow, and decreasing neuroinflammation. This study will scientifically evaluate the effectiveness of *Bala Taila and Pippalyadi Taila Nasya* in TTH (*Vataja Shirashoola*) based on objective clinical parameters. If the outcome is positive, it can open the door for the use of *Nasya* therapy as an evidence-based therapeutic approach for headache treatment.

Although TTH is commonly prevalent worldwide and associated with *Vataja Shirashoola*, limited clinical trials have compared the effectiveness of *Nasya* therapy in the treatment of headaches. Although the individual effectiveness of *Bala Taila Nasya* has been studied in earlier research, but no comparative study with *Pippalyadi taila nasya* has been done to determine which of these products is better.

In addition, the earlier research lacked objective measuring instruments such as pain intensity rating, assessment of QoL, and assessment of ROM, which are required for scientific evidence of *Ayurvedic* treatments. This study attempts to bridge the gap by conducting a randomised controlled comparison of the two preparations using standardised measuring parameters. This current study aims to examine and compare the effectiveness of *Pippalyadi Taila Nasya and Bala Taila Nasya* in the management of *Vataja Shirashoola* (TTH).

Objectives

The primary objective of this study is to evaluate and compare the effectiveness of *Pippalyadi Taila Nasya* and *Bala Taila Nasya* in reducing pain intensity in patients with *Vataja Shirashoola* (TTH).

The secondary objectives include assessing improvements in neck mobility, QoL, and pain assessment of headache.

Hypotheses: Null hypothesis (H_0): There is no significant difference in the efficacy of *Bala Taila Nasya* and *Pippalyadi Taila Nasya* in the management of TTH.

Alternate hypothesis (H_1): There is a significant difference in the efficacy of *Bala Taila Nasya* and *Pippalyadi Taila Nasya* in the management of TTH.

REVIEW OF LITERATURE

The TTH is a common neurological disorder in millions of individuals worldwide. *Ayurveda* categorises it as *Vataja Shirashoola* (headache due to *Vata Dosha* aggravation), with dietary and lifestyle modification being crucially significant. Inchekar VA, emphasised the role of the *Vata- and Pitta*-pacifying diets in preventing and managing headaches [17]. *Nasya* therapy, a fundamental head disease treatment, has been thoroughly discussed by Swati C et al., with special reference to its ability to influence trigeminal nerve pathways directly and cerebral circulation [18]. Shukla RK et al., depicted the restoration of neurological function in paralysis by *Nasya*, emphasising its applicability in headache treatment [19]. Lal B and Mishra N studied the analgesic and neuroprotective activity of *Embelia ribes*, a drug in most *Nasya* formulations [20]. Current research by Cathcart S et al., linked stress and muscle tension to headache mechanisms, correlating with Ayurvedic concepts [21]. Mahajan SU et al., emphasised *Shiroabhitapa* (prolonged headache) control by *Nasya* and lifestyle correction, reasserting its effectiveness [22] [Table/Fig-1].

MATERIALS AND METHODS

A RCT will be done to determine if the efficacy of *Pippalyadi Taila Nasya* is superior to *Bala Taila Nasya* in the management of *Vataja Shirashoola* (TTH) from January 2024 to December 2025 The research has been approved by Institutional Ethical Clearance (IEC) by MGACH & RC, an associate of DMIHER, who is deemed to be a university. It has been approved under Reference No: MGACHRC/IEC/Sep-2023/741, dated 18.09.2023. The present study is registered with the Clinical Trial Registry of India (CTRI) under registration number CTRI/2023/10/058733, dated 17/10/2023.

Informed written consent will be obtained from all the participants prior to enrollment. The consent will be in both English and Marathi so that the participants know the purpose of the study, the procedures, the potential benefits, and the risks. Participants can withdraw from the study at any point without adversely affecting their continued care or treatment at the institution.

Inclusion criteria: The study will be conducted on 18-60-year-old patients of either gender, clinically diagnosed as TTH/Vataja

Author(s)	Title	Findings	Summary
Inchekar VA, 2019 [17]	A review on diet therapy for prevention and management of Vataj and Pittaj Shiroroga through Ayurveda with special reference to migraine	Diet modifications can help regulate Vata and *Pitta Dosha*, preventing headaches	Dietary interventions in Ayurveda can reduce headache frequency by balancing *Doshas*
Swati C, et al., 2016 [18]	A critical review on nasal drug delivery system in ayurveda: *Nasya*	*Nasya* therapy directly influences the nervous system, aiding in headache relief	*Nasya* is an effective alternative therapy for headache disorders and sinus-related issues
Shukla RK et al., 2024 [19]	The ayurvedic management of spastic paralysis wsr Pakshaghata: A case report	*Nasya* therapy improves neurological function and circulation in paralytic conditions	The study supports *Nasya*'s role in strengthening cranial nerves and reducing neuroinflammation
Lal B and Mishra N, 2014 [20]	Importance of *Embelia ribes*: An update	*Embelia ribes* have neuroprotective and analgesic properties that are beneficial for headaches.	The herb *Embelia ribes* shows promise in treating headaches and nervous disorders.
Cathcart S et al., 2010 [21]	Stress and Tension-Type Headache (TTH) mechanisms	Chronic stress and muscle tension contribute significantly to headache severity	Headache severity is linked to chronic stress, muscle tightness, and neurovascular changes
Mahajan SU et al., 2021 [22]	*Shiroabhitapa*: A persisting ailment	*Shiroabhitapa* (chronic headache) can be managed with *Nasya* and lifestyle modifications	Ayurveda offers holistic headache management through *Nasya* and lifestyle adjustments

[Table/Fig-1]: Provides an overview of previous work on headache treatment, *Nasya* treatment, and Ayurveda treatment that is useful for developing the basis of future work [17-22].

Shirashoola as per ICHD-3 and Ayurvedic diagnostic criteria. Only Madhyam Satwa (middle mental strength), diagnosed by Satwa Parikshan, and suitability for *Nasya Karma*, as per Ayurvedic criteria, will be taken. Volunteers with mild to medium grade headache severity as per NRS willing to provide written informed consent to adhere to the study protocol will be taken.

Exclusion criteria: Patients with severe headaches or pre-existing chronic systemic diseases such as hypertension, diabetes, epilepsy, stroke, cancer, or psychiatric disorders. Pregnant or lactating women, alcoholics, smokers or substance abusers, and secondary headache patients resulting from trauma, infection, or structural lesions of the brain will be excluded. Patients undergoing any other concomitant headache treatment or having nasal pathology contraindicated to the treatment of *Nasya* therapy will be excluded from the study.

Sample size calculation: The study will involve 60 patients divided evenly into two groups of 30 and randomised. The sample size was computed based on earlier research on *Nasya* therapy and headache treatment, so the outcome measures were statistically significant [16].

Sample size by Cohen's effect size by comparing two means (QoL)

Effect size=d=$\frac{\mu_2-\mu_1}{\sigma}$ = 0.80 (Estimated) for Periapical Index score

Considering large effect size difference = 0.85 (Large effect size)

Sample size N= $(\frac{1+r}{r})\frac{(Z_{1-\alpha/2}+Z_{1-\beta})^2}{d^2}+\frac{Z^2_{1-\alpha/2}}{2(1+r)}$

$Z_{1-\alpha/2}$ at 5 % level of significance = 1.96

$Z_{1-\beta}$ at 80 % Power = 0.84

Ratio allocation (Group 2 /Group 1) = 1

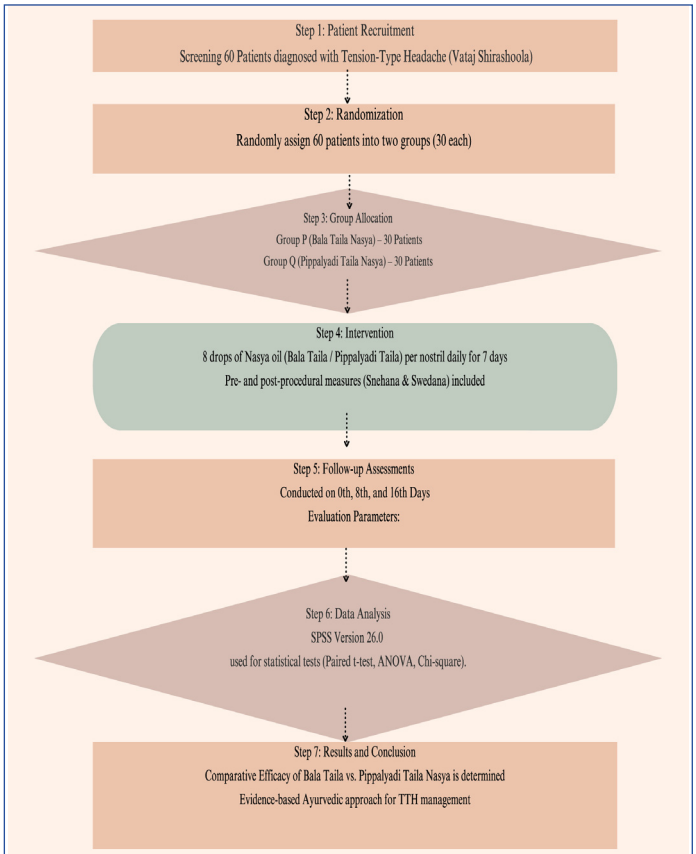
Sample size n= $(\frac{1+1}{1})\frac{(1.96+0.84)^2}{0.95^2}+\frac{(1.96)^2}{2(1+1)}$ = 26 per group.

Total 26 samples required per group.

Considering dropout of 20%

Sample size 30 per group

Total 60 samples. Trial design flowchart is shown in [Table/Fig-2].



[Table/Fig-2]: Depicts the trial design summary, Randomised Controlled Trial (RCT), patient recruitment to results analysis, screening, randomisation, intervention, follow-up assessments, statistical analysis, and conclusion.

Study Procedure

A total of 60 patients diagnosed with TTH will be enrolled and randomly assigned to two groups, Group P (treated with *Bala Taila Nasya*) and Group Q (treated with *Pippalyadi Taila Nasya*), by the computer-generated method of randomisation. *Bala Taila* is employed as a control since it also possesses a well-established clinical history of managing neurological disease and headache disorders [23]. It is an Ayurvedic standard treatment due to its neuroprotective, *Vata*-pacifying, and analgesic activity. *Pippalyadi Taila*, with its *Pippali* and *Saindhava Lavana*, is anticipated to have a greater extent of pain relief and anti-inflammatory action than *Bala Taila*, which already possesses an established efficacy [24,25]. The current trial seeks to determine whether or not the *Pippalyadi Taila* confers additional benefits over the conventional *Bala Taila Nasya* treatment. Pain relief improvement, mobility of the neck improvement, and QoL will be the study outcomes. The intervention period would be for seven days with once-daily *Nasya* therapy. Follow-up assessment would be administered on the 0th, 8th, and 16th days using standardised scales like NRS, ROM measure, and QoL rating scales [26,27]. A cautious scientific assessment of the study would be made to examine the efficacy of *Nasya* therapy in reducing headaches Study methodology is given in [Table/Fig-3].

Intervention description: The trial evaluates the efficacy of two *Nasya* preparations in managing TTH (*Vataja Shirashoola*). Intervention is intranasal administration of medicated oils as per traditional Ayurvedic practice.

Group P patients will receive *Bala Taila Nasya*, and Group Q patients will receive *Pippalyadi Taila Nasya.* Each patient will be instilled with eight drops of the respective *Nasya* oil in each nostril once a day for seven days. The administration will be provided in the morning before

Groups	Sample size	Treatment	Frequency	Treatment Period	Assessment	Follow-ups
Group P (*Bala Taila Nasya*)	30 Patients	*Bala Taila Nasya* (Intranasal Oil Therapy)	8 drops in each nostril daily	7 days	Pain intensity (NRS), Neck Mobility (ROM), Quality of Life (QoL)	0^{th}, 8^{th}, and 16^{th} days
Group Q (*Pippalyadi Taila Nasya*)	30 Patients	*Pippalyadi Taila Nasya* (Intranasal Oil Therapy)	8 drops in each nostril daily	7 Days	Pain Intensity (NRS), Neck Mobility (ROM), Quality of Life (QoL)	0^{th}, 8^{th}, and 16^{th} days

[Table/Fig-3]: Summarises the study methodology, including the sample size, treatment type, frequency, treatment period, assessment parameters, and follow-up schedule for both groups.

breakfast or after food digestion as per classical Ayurvedic practice. The oil is prewarmed slightly to around 37°C before administration for enhanced absorption and therapeutic effect. The patient will be advised to be in a recumbent posture for three to five minutes after instillation to facilitate enhanced penetration of medicated oil. Local *Snehana* and *Swedana* will be administered before the *Nasya* therapy to prepare the nasal passages for optimal absorption. The patient will be supine with the head extended backwards at an angle of 45° for optimal nasal absorption. Patients will be instructed to stay in this position for a few minutes following the administration of the *Nasya* oil to facilitate maximum penetration of the drug.

After the procedure, patients will be instructed to refrain from excessive talking, sneezing, strenuous exercise, and cold air for at least one hour to avoid irritation and proper medication absorption. They will be observed for any possible side-effects like mild nasal irritation, sneezing, or over-discharge of mucus, and any side-effects will be recorded. The intervention will be measured in terms of the reduction in pain intensity (NRS), enhancement in neck mobility (ROM), and improvement in QoL (QoL scores). The intervention is based on the classical Ayurvedic concepts of *Nasya Karma*, and the goal is to reduce *Vata Dosha* imbalance, enhance neurological function, and bring long-term relief from chronic headaches.

Preparation of *Nasya* Therapy

Preparation of *Nasya* therapy is carried out systematically to achieve the maximum absorption of medicated oils and to achieve maximum therapeutic effects on TTH (*Vataja Shirashoola*) [28].

Patient Preparation

Local *Snehana and Swedana* are done prior to *Nasya* administration to soften and dilate the nasal channels. *Snehana* is done with a gentle head, neck, and face massage with an appropriate medicated oil to increase circulation. In contrast, *Swedana* uses gentle herbal steam near the nose to facilitate easy penetration. The patient will be positioned in a supine position with the head inclined backwards by 45° for the efficient administration of the drug [29].

Preparation of Medicated Oils

Two *Nasya* preparations are used in the current study. *Bala Taila* (in Group P), which is prepared from *Bala (Sida cordifolia*) and other Vata-pacifying medicines, is prepared in Tila Taila (sesame oil), which is neuroprotective in action. *Pippalyadi Taila* (in Group Q), which is prepared from *Pippali (Piper longum), Saindhava Lavana* (Rock salt), and *Tila Taila,* is traditionally used for its analgesic and anti-inflammatory action. Both the oils are authenticated and standardised as per Ayurvedic Pharmacopoeia standards before use [Table/Fig-4-9].

Administration Procedure

All the patients will receive eight drops of the provided *Nasya* oil in both nostrils daily for seven days and warmed to body temperature (around 37°C) before use to increase the absorption rate [Table/Fig-10]. The patient will be requested to gently breathe in after installation and lie on his back for a few minutes to enable proper penetration [30].

Monitoring and Postprocedure Care

Post-*Nasya* therapy, the patients are advised not to talk much, sneeze, do heavy work, or take cold air for at least an hour.

[Table/Fig-4]: Photograph of Pippali (*Piper longum*) used in preparation of *Pippalyadi Taila*.

[Table/Fig-5]: *Saindhava Lavana*.

[Table/Fig-6]: *Tila Taila*.

[Table/Fig-7]: Image of preparation of oil (a).

[Table/Fig-8]: Image of preparation of oil (b).

[Table/Fig-9]: Sample of prepared oil.

[Table/Fig-10]: *Nasya* procedure.

Observation for any minor nasal irritation, discharge of mucus, or dizziness is made, and side-effects are recorded and treated accordingly. This preparatory procedure adheres to Ayurvedic *Nasya* traditions to provide maximum therapeutic effect in relieving *Vata Dosha* imbalance and enhancing neurological function [31].

Outcomes of the Study

The primary outcome of the study is the reduction in pain severity, assessed using the NRS [26]. The secondary outcomes include neck range recovery, measured by ROM, and QoL improvement, which were assessed using validated QoL questionnaires [27]. Other secondary outcomes are the frequency of headaches, duration of action (how long the effects last), and the frequency of relapse (return of symptoms). These parameters will evaluate the clinical effectiveness of *Bala Taila Nasya and Pippalyadi Taila Nasya* in managing TTHs (*Vataja Shirashoola*).

Pain Measurement Intensity: Pain intensity will be assessed using the NRS. The NRS scores pain from 0 to 10, with 0 indicating no pain and 10 indicating the worst pain possible. It offers an objective measure to assess the decrease in pain during treatment [32].

Neck Mobility Test: Restricted mobility of the neck is a common symptom of TTH. ROM measurement with a goniometer will be utilised to measure cervical spine flexibility and ROM. The neck's rotation, flexion, and extension will be measured before and after to determine the treatment's impact on reducing muscle tension and enhancing mobility [21].

Quality of Life (QoL) Appraisal: A standardised QoL questionnaire will be used to measure the impact of headaches on activity, mental wellbeing, sleep, stress, and work. This will determine how the therapy improves overall functionality and lifestyle [33].

Follow-Up Tests: Relapse of headache spells, change in pain intensity, or side-effects will be noted. This methodical assessment will compare *Bala Taila Nasya and Pippalyadi Taila Nasya* with an objective measurement of their efficacy in treating TTHs. Every participant will receive a 7-day treatment, with assessments on Day 0 (baseline), Day 8 (following treatment), and Day 16 (follow-up assessment). The duration allows for maximum observation of the effectiveness of treatment within a short duration and tracking of recurrence patterns.

Data Collection, Management, and Analysis Methods: Data will be gathered through validated clinical assessment instruments like NRS for pain severity, neck ROM, and QoL scales for well-being.

Data of every participant will be entered in an anonymous Case Report Form (CRF) and electronically in a password-protected database for data security reasons. Data will be double-verified for accuracy, and missing values will be addressed through standard statistical imputation methods.

STATISTICAL ANALYSIS

The data analysis will be done through Statistical Package for the Social Sciences (SPSS), version 26.0. Intra-group and inter-group differences will be tested for significance using t-tests, ANOVA, and Chi-square tests. Descriptive statistics will supply baseline results, and comparative analysis will determine if the two *Nasya* interventions are effective. A p-value of < 0.05 will be regarded as statistically significant, indicating that the differences between results are unlikely to be coincidental. A total of 95% confidence intervals will be used to be statistically valid.

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