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Research Protocol

Ayurveda Section

Efficacy of Tulsi-Turmeric Oil Pulling versus Sesame Oil Pulling on Temporomandibular Joint Movement in Oral Submucous Fibrosis (*Vata Pitta* dominant *Tridosaja Sarvasara Mukharoga*): A Randomised Controlled Trial Protocol

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ABSTRACT

Introduction: Oral Submucous Fibrosis (OSMF) is a chronic oral condition characterised by inflammation and fibrosis, leading to restricted mouth opening, burning sensations, loss of taste, and ulcerations. Chewing betel nut is a significant risk factor, and OSMF carries a 2-30% risk of progressing to carcinoma, with a prevalence of 0.5% in the Indian subcontinent, predominantly affecting females. Current treatments are often ineffective and have adverse effects, prompting interest in natural remedies such as *Tulsi* and Turmeric, which may alleviate symptoms and effectively manage the condition.

Need of the study: Current treatments for OSMF are often limited and have adverse effects, instigating interest in natural remedies like *Tulsi* and Turmeric, which may alleviate symptoms and manage the condition effectively. Exploring alternative therapies such as oil pulling, a traditional practice in Ayurveda, may offer new hope for patients. Oil pulling is a natural, non-invasive, and cost-effective treatment. By comparing two different oils-*Tulsi*-Turmeric and Sesame-this study aims to identify the most effective oil for improving mouth opening, thus providing evidence-based guidance for practitioners and patients.

Aim: The present study compares the efficacy of *Tulsi*-Turmeric oil pulling versus Sesame oil pulling on Temporomandibular Joint (TMJ) movement in OSMF patients with *Vata Pitta* dominant *Tridosaja Sarvasara Mukharoga* (a disease affecting the whole oral cavity).

Materials and Methods: A prospective randomised standard control double-blind superiority clinical trial (RCT) will be conducted at the *Shalakya Tantra* Department of Mahatma Gandhi Ayurved College, Hospital and Research Centre, Salod Wardha, Maharashtra, India, from October 2023 to October 2025. Sixty participants will be divided into two groups of thirty participants each. One group will receive *Tulsi*-Turmeric oil pulling, while the other will receive Sesame oil pulling for thirty days. The TMJ movement assessment will involve the evaluation of the range of movements laterally, anteroposteriorly, and vertically, along with palpation of the TMJ and surrounding muscles to identify tenderness. Other assessments will include IID scoring, cheek flexibility, and Visual Analog Scale (VAS) scores before and after the intervention. Descriptive statistics will summarise demographic data, and results will be expressed as mean±standard deviation for continuous variables and frequencies for categorical variables. The paired t-test and unpaired t-test will be applied for intra-group and inter-group comparisons. A p-value of <0.05 will be considered significant.

Keywords: Ayurveda, Range of motion, Cheek flexibility, Precancerous condition, Betel nut

INTRODUCTION

OSMF is a chronic, debilitating condition characterised by fibrosis of the oral cavity, primarily affecting the subepithelial layer. It predominantly occurs in individuals of Asian descent and is recognised as a collagen metabolic anomaly often induced by the prolonged use of areca nut and its products. This irreversible condition leads to stiffness of the oral mucosa and may also involve the pharynx and oesophagus, significantly increasing the risk of malignant transformation. Symptoms of OSMF include whitening of the oral mucosa, reduced tongue mobility, papillary atrophy, depigmentation, progressive limitation of mouth opening, and uvular contraction [1].

The aetiology of OSMF is multifactorial, involving chronic betel nut and tobacco use, excessive consumption of spicy food, genetic predispositions, immune reactions, smoking, alcohol use, and nutritional deficiencies [2]. The World Health Organisation classifies it as an oral precancerous condition due to its high potential to develop into cancer [3]. Schwartz first reported it in 1952 among East African Indians as "atrophic idiopathic tropical mucosae oris," which was later named "OSMF" by Joshi in India [4,5]. The malignant transformation rate of OSMF is approximately 6%, with a prevalence of 0.5%, mainly in the Indian subcontinent and with higher susceptibility among females [6].

In Ayurveda, OSMF does not correspond precisely to any known oral diseases and is therefore considered an *Anukta Vyadhi* (unclassified disease). However, symptoms akin to OSMF are scattered throughout *Ayurvedic* texts, describing it as a *Tridoshaja* disorder primarily influenced by the *Vata* and *Pitta doshas*. Traditional *Ayurvedic* practices such as sudation (*Swedana*), oil pulling (*Gandusha*), gargling (*Kavala*), and nasal therapy (*Nasya*) are suggested for managing these symptoms [7]. *Tulsi* (*Ocimum sanctum*), revered as the 'Queen of Herbs,' exhibits numerous medicinal properties, including antioxidant, anti-inflammatory, and analgesic effects, mainly due to its constituents like eugenol and methyl chavicol. It effectively blocks inflammatory pathways by inhibiting cyclooxygenase and lipoxygenase [8]. Similarly, curcumin in turmeric shows promising results in reducing inflammation-related enzymes and free radical activities, making it a valuable component in treating conditions like OSMF [9]. The present study aims to explore the therapeutic efficacy of *Tulsi*-Turmeric oil pulling versus

Sesame oil pulling in managing OSMF, potentially offering a cost-effective treatment strategy for this precancerous condition.

Primary objective:

- To assess the clinical improvement in TMJ movements using *Tulsi*-Turmeric oil pulling compared to Sesame oil pulling and coconut oil pulling.

Secondary objectives:

- To evaluate the reduction in symptoms such as pain and burning sensation associated with OSMF for each oil-pulling method.
- To identify and compare any adverse effects experienced by patients using each oil-pulling method.

Null hypothesis: *Tulsi-Turmeric* oil pulling is not as efficacious as Sesame oil pulling in improving TMJ movement when treating oral submucosal fibrosis.

Alternate hypothesis: *Tulsi-Turmeric* oil pulling is equally or more efficacious than Sesame oil pulling in improving TMJ movement when treating oral submucosal fibrosis.

REVIEW OF LITERATURE

This literature review aims to comprehensively analyse the existing knowledge on the therapeutic potential of *Tulsi* (*Ocimum sanctum*) and turmeric (Curcuma longa) in managing OSMF. By critically examining relevant studies, this review seeks to uncover key insights, evaluate their efficacy, and identify gaps in current research. The findings will contribute to a deeper understanding of their role in this condition, laying the groundwork for future investigations and potential clinical applications. The previous studies related to OSMF are mentioned below in [Table/Fig-1] [10-17].

MATERIALS AND METHODS

A prospective, randomised, controlled, double-blind superiority clinical trial (RCT) will be conducted at the *Shalakya Tantra* Department of Mahatma Gandhi Ayurved College, Hospital and Research Centre, Salod (H), Maharashtra, India, from October 2023 to October 2025. Ethical approval from the institutional ethical committee has been obtained with registration number MGACHRC/IEC/Sep-2023/742, and registration has been completed on the Clinical Trials Registry of India (CTRI number: CTRI/2024/01/061182). Participants will be informed about the study's nature, risks, and benefits, and written informed consent will be obtained from each participant before their inclusion in the trial.

Inclusion criteria:

- Patients aged 18 to 60 years, with a history of consuming areca nut in various forms and experiencing a reduced mouth opening of 25 to 35 mm with stage I and II grade [18].
- Patients with palpable fibrotic bands, blanched oral mucosa, and associated symptoms of oral ulceration or burning sensation.

Exclusion criteria:

- Patients with a history of malignancy, oral lesions other than OSMF, severe trismus {Interincisal Distance (IID) <13 mm}, or advanced disease with premalignant or malignant changes.
- Generalised fibromatosis or chronic debilitating conditions such as uncontrolled diabetes mellitus, uncontrolled hypertension, or HIV infection.
- Patients currently undergoing pharmacological or surgical treatments for OSMF or those with systemic diseases will also be excluded from the study.
- All participants will be counselled on lifestyle modifications, such as the cessation of smoking, chewing tobacco, gutka, betel nut, areca nut, and alcohol consumption.

Sample size: The sample size was calculated utilizing the difference in mean values for the variable mouth opening as a primary variable between pre- and post-treatment of oil pulling [19].

Primary variable:

Mean±SD in mouth opening in the oil pulling group at baseline= 21.2±3.1=1.3

Mean±SD in mouth opening group at post=23.4±3.7 [19]

Pooled standard deviation = (3.1 +3.7)/2=3.4

Mean difference (δ)=2.2

Formula using mean difference:

$$n1 = n2 = \frac{(Z\alpha + Z\beta)^2 \sigma^2}{(\delta)^2}$$

Zα=1.96 at 5% error and CI at 95%
Zβ=0.84=power at 80%

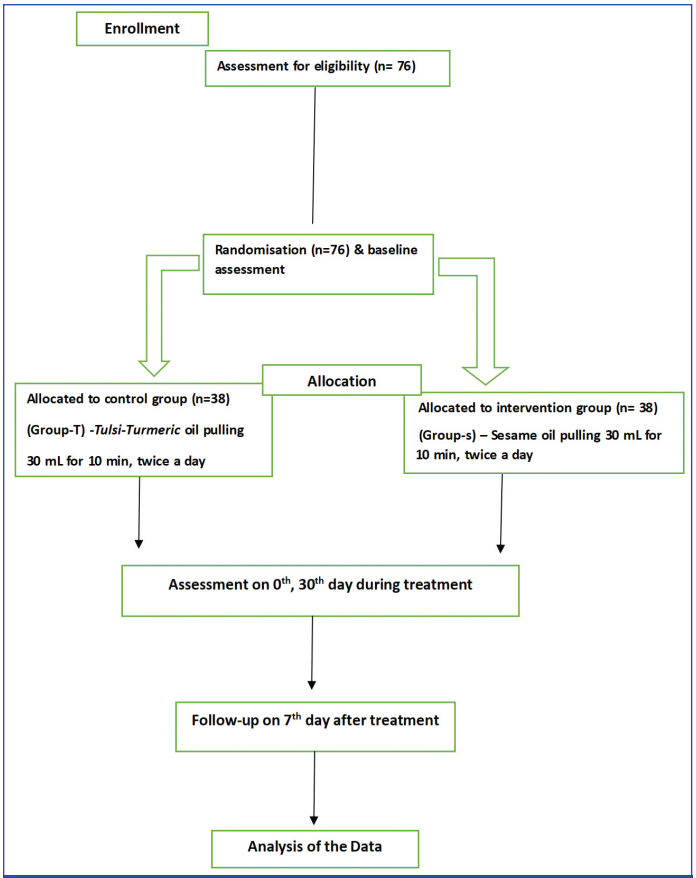
n= 38 per group.

Total sample required= 2×38= 76.

The patient's allotment and allocation are depicted in [Table/Fig-2].

S. No.	Authors name	Title of the study	Result
1.	Mobeen S et al., [10]	a novel herbal paste formulation of turmeric, *tulsi*, and honey for the treatment of Oral Submucous Fibrosis (OSMF)	Statistically significant differences were observed in the study subjects compared to the control group, including changes in mouth opening, tongue protrusion, sensations of burning, mucous membrane blanching, and a reduction in palpable fibrous bands. Top of Form
2.	Panya G et al., [11]	*Ayurvedic* management of oral sub mucous fibrosis.	Ayurveda treatment is helpful to subside inflammation and ulceration preventing further progress, increasing suppleness of the stiffed oral tissue and in turn reverses fibrosis of submucosa and oral mucosa to overcome the disease
3.	Deepti B et al., [12]	Efficacy of topical *tulsi* (*ocimum sanctum*) paste for the management of -A clinical study.	*Tulsi* paste showed a significant reduction in the burning sensation and improvement of the mouth opening thereby proving to be a safe and promising medicament for OSMF.
4.	Rizvi D et al., [13]	Efficacy of curcumin gel and *tulsi* gel in OSMF darakhshan.	The study revealed that both the test drugs are effective in reducing the symptoms of OSMF, but curcumin was found to be more effective in the reduction of the symptoms, more effectively in the burning sensation.
5.	Virani D et al., [14]	Assessment of the utility of *tulsi* and turmeric in treatment of OSMF: A clinical study.	The combination of *Tulsi* and Turmeric can be considered as a better alternative to the modern treatment modality in the management of all grades of OSMF.
6.	Gupta T et al., [15]	Clinical evaluation of the role of *Tulsi* and Turmeric in the management of OSMF: a pilot, prospective observational study.	*Tulsi* and turmeric along with lifestyle modification is a safe and efficacious remedy for the treatment of all grades of OSMF in all age groups with no limitation to its use.
7.	Madhulatha G et al., [16]	Tulasi a magical herb and a boon for management of OSMF: a clinical study.	The study concludes that Tulasi can be used as a main treatment modality in the management of patients with OSMF.
8.	Srivastava A et al., [17]	Clinical evaluation of the role of *tulsi* and turmeric in the management of OSMF: A pilot, prospective observational study.	*Tulsi* and turmeric offer a safe and efficacious combination of natural products available for the symptomatic treatment of OSMF.

[Table/Fig-1]: Literature on Oral Submucous Fibrosis (OSMF) [10-17].



[Table/Fig-2]: CONSORT flow diagram.

The herbs (*Tulsi* and Curcumin) will be powdered and infused into oil at the pharmacy lab of Mahatma Gandhi *Ayurvedic* College under the supervision of an *Ayurvedic* specialist, following pharmacognosy studies. The sesame oil will be procured from a reliable source.

Drug preparation: A typical method of Siddha oil preparation (1:4:16) will be followed as per *Sneha Kalpana* mentioned in the *sharangdhara Samhita*. (*sha. ma*. 9/17) [20].

To prepare *Tulsi*-Turmeric oil, a decoction using 2.5 kg of *Tulsi* leaves and 3 kg of Turmeric will be made. Boil 84 litres of water, add the *tulsi* and turmeric, and simmer until the water reduces by half. Strain the decoction and add it to 21 litres of heated sesame oil. Evaporate the water, cool, filter, and store the oil in a glass jar away from direct sunlight for several months of therapeutic use.

Intervention: All enrolled patients will be assigned to either Group-T (Intervention group) or Group-S (Control group). Group-T will receive lukewarm *Tulsi*-Turmeric oil, while Group-S will receive Tila Taila (Sesame oil). They will be instructed to hold 10-15 mL of the oil in their mouth for 10 minutes twice daily and to refrain from eating or drinking for 15 minutes afterwards [Table/Fig-3].

Group	Sample size	Intervention	Dose and frequency	Duration	Follow-up
T	38	*Tulsi*-Turmeric oil pulling	30 mL for 10 min, twice a day	30 days	15th day 30th day
S	38	Sesame oil pulling	30 mL for 10 min, twice a day	30 days	15th day 30th day

[Table/Fig-3]: Grouping and Posology.

An independent statistician will generate the allocation sequence using computer-generated tables. Clinical researchers or study coordinators will enrol participants, ensuring they meet the inclusion criteria while remaining unaware of the allocation sequence. The research coordinator, blinded to the sequence, will assign participants to intervention groups using the pre-generated sequence. These steps will ensure an unbiased and transparent allocation process.

Primary outcome: The primary outcome will be the improvement in mouth opening (IID), using clinical examination tools such as a ruler or a goniometer to measure mouth opening. TMJ movements, particularly lateral Anterior-Posterior (AP) movement, will include measuring the range of motion-specifically lateral excursion (10-12 mm), protrusion (6-9 mm), and retrusion (3 mm) [21]. Key elements will include evaluating symmetry and deviations during movement, documenting any pain or discomfort experienced, and assessing audible joint sounds (e.g., clicking or popping) that may indicate dysfunction. Additionally, palpation will help identify tenderness in the TMJ and surrounding muscles at baseline (i.e., day 0), on the 15th day, and on the 30th day.

Objective parameters will include the IID scoring, which measures the distance between the mesial angles of the upper and lower central incisors using a Vernier calliper. Scores will be based on specific ranges: 17-20 mm (Score 6), 21-24 mm (Score 5), 25-28 mm (Score 4), 29-32 mm (Score 3), 33-36 mm (Score 2), 37-40 mm (Score 1), and 41 mm or above (Score 0) [22].

Secondary outcome: Secondary outcomes include the reduction of oral burning sensation and regression of fibrotic bands, as well as adherence to lifestyle modifications (e.g., cessation of areca nut consumption). These will be evaluated based on the severity of symptoms such as burning sensation, mouth stiffness, and difficulty in eating or speaking, measured through self-reports using standardised symptom questionnaires such as the Oral Health Impact Profile (OHIP-14) [23] or the Visual Analog Scale (VAS) [24] at the same time points.

Cheek flexibility will be measured by assessing the distance from the maxillary incisal midline to the cheek retractor during retraction, with gender-specific normal ranges: males (35-45 mm) and females (30-40 mm). Scores will be assigned as follows: Less than 20 mm (Score 2), 20-30 mm (Score 1), and 30 mm and above (Score 0) [25].

Subjective parameters will assess various symptoms impacting oral health, such as burning sensation, excessive salivation, and intolerance to spicy foods [26], using tools like the VAS to measure pain intensity, as mentioned in [Table/Fig-4]. Clinicians will also evaluate gustatory sensations, observe the colour of the oral mucosa, measure the dimensions of ulcers, and palpate the mucosa to provide a comprehensive assessment of the patient's condition. The clinical relevance of these efficacy and harm outcomes is

S. No.	Signs and symptoms [26]	Score
1	**Mukhadaha: (Burning sensation)**	
	Nil	0
	On taking spicy food	1
	Continuous	2
2	**Lalasrava: (Excessive salivation)**	
	Normal	0
	Altered	1
	Decreased	2
3	**Mukha Vedana (pain in mouth)**	
	Nil	0
	While opening the mouth	1
	Continuous	2
4	**Katu rasa asahishnuta: (Intolerance to spicy foods)**	
	Nil	0
	Mild	1
	Moderate	2
	Severe	3
5	**Colour of oral mucosa**	
	Pink normal	0
	Red or deep pink	1
	Pale white	2
	Blanched white	3

6	Ulceration in mouth	
	Nil	0
	Mild	1
	Moderate	2
	Severe	3

[Table/Fig-4]: Comprehensive assessment of signs and symptoms.

strongly recommended to ensure a thorough evaluation of the treatment's impact on both the functional and metabolic aspects of patients with OSMF.

All the above-mentioned parameters will be evaluated at baseline (i.e., day 0), on the 15th day, and on the 30th day.

Severity assessment:

Mild severity: Lower total scores (0-6) indicate fewer or less severe symptoms.

Moderate severity: Middle-range scores (7-12) suggest moderate symptoms.

Severe severity: Higher scores (13 or above) reflect more severe symptoms or greater dysfunction.

STATISTICAL ANALYSIS

Consent or assent: Plans for communicating necessary protocol modifications (e.g., changes to eligibility criteria, outcomes, analyses) to relevant parties (e.g., investigators, Research Ethics Committees (REC)/Institutional Review Boards (IRB), trial participants, trial registries, journals, regulators) are not applicable.

Confidentiality: Personal information concerning potential and enrolled participants will be collected using unique identifiers to ensure anonymity. Data will only be shared with authorised personnel directly involved in the study and will be securely stored in locked file cabinets or password-protected electronic databases. Confidentiality measures will be strictly adhered to throughout the trial, following guidelines set by the Independent Ethics Committee (IEC) and relevant regulatory authorities.

Declaration of interests: Principal investigators overseeing the entire trial and at each study site will transparently disclose any financial or other competing interests that could influence the study's integrity or the interpretation of results.

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