

Efficacy and Safety of Herbal Mouthwashes in Preventing Gingivitis: A Multi-Center Randomized Trial

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ABSTRACT

There is a need for efficient and well-tolerated preventive strategies for gingivitis because it is one of the most common inflammatory disorders impacting oral health. This 4-week randomized clinical experiment compared chlorhexidine, an anti-gingival mouthwash, to a herbal mouthwash to see which was more effective and safer. At baseline, 2 weeks, and 4 weeks after treatment, 120 people with mild to moderate gingivitis were evaluated clinically; those in the chlorhexidine group were compared to those in the herbal group. At the conclusion of the intervention, there was no statistically significant difference between the two groups, and both groups showed substantial reductions in Gingival Index and Plaque Index scores. On the other hand, the herbal mouthwash was much more tolerable, with far less side effects. These results indicate that herbal remedies can be a safer and more efficient substitute for chlorhexidine in the treatment of gingivitis and in enhancing the results of dental hygiene routines.

Key Words:

Herbal Mouthwash, Gingivitis, Chlorhexidine, Randomized Trial, Plaque Index, Gingival Health

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1. INTRODUCTION

One of the most common oral health issues worldwide, gingivitis affects people of all ages and is frequently the first sign of periodontal disease. The buildup of dental plaque and insufficient oral hygiene habits are the main causes of gingivitis, which is characterized by inflammation, bleeding, and pain of the gingival tissues¹. Although chemical mouthwashes like chlorhexidine are often used in conventional management, they often come with unwanted side effects such as discoloration, altered taste, and mucosal irritation, even when they are effective². Due to their possible antibacterial, anti-inflammatory, and antioxidant characteristics, herbal mouthwashes are attracting more and more attention as a safer and more natural alternative to conventional dental

hygiene products³. Examining the effectiveness and safety of a herbal mouthwash in contrast to chlorhexidine, this study seeks to determine if plant-based formulations can provide a less harsh alternative to chlorhexidine for the prevention of gingivitis⁴.

1.1. Background information

The first stage of periodontal disease, gingivitis is an inflammatory disorder of the gingival tissues that can be healed. It affects a large percentage of the world's population. Dental plaque, a biofilm full of harmful microbes, builds up and causes irritation, bleeding, and pain in the gums if not cleaned properly⁵. Chemical adjuncts, such mouthwashes, are often advised to augment mechanical plaque management, which is still the bedrock of dental care, with brushing and flossing⁶. Because of its powerful antibacterial activities, chlorhexidine has long been considered the "gold standard" antiseptic mouthwash. However, its therapeutic effectiveness is restricted by well-documented adverse effects, such as tooth discoloration, changed taste, and mucosal irritation⁷. Herbal and plant-based formulations, which lack the negative effects of synthetic medicines but have natural antibacterial and anti-inflammatory capabilities, have recently attracted a lot of attention due to these shortcomings⁸. There is a lack of comparison data based on rigorous, multi-center trials, despite the fact that ingredients like Aloe vera, neem, and turmeric have demonstrated encouraging promise in enhancing gingival health. In order to advocate for the use of herbal mouthwashes as part of preventative dental care and to provide patients with safer, more pleasant alternatives to traditional chemical rinses, it is crucial to understand their clinical efficacy and safety.

1.2. Statement of the problem

Common chemical mouthwashes, such chlorhexidine, have limitations that make it difficult to prevent and control gingivitis, despite the fact that it is a major oral health concern driven by plaque buildup and insufficient daily hygiene practices⁹. Despite chlorhexidine's well-known antibacterial properties, it is often associated with side effects such as tooth discoloration, altered taste, and irritation of the mucosal surfaces. As a result, patients are less likely to comply with the treatment and accept it in the long run. Herbal mouthwashes have recently gained popularity as an alternative to traditional chemical formulations for oral hygiene because of the growing need for solutions that are safer, more effective, and less likely to cause adverse effects¹⁰. Nevertheless, there is a lack of strong clinical evidence comparing the two. This lack of data highlights the importance of conducting comprehensive, multi-center clinical trials to find out if herbal mouthwashes may prevent gingivitis just as well as conventional mouthwashes while reducing side effects, making them a more practical and pleasant choice for patients' regular dental hygiene.

1.3. Objectives of the study

- To evaluate the effectiveness of the herbal mouthwash in reducing gingival inflammation among adults with mild to moderate gingivitis over a 4-week period.
- To compare the plaque reduction achieved by the herbal mouthwash with that of chlorhexidine across baseline, 2-week, and 4-week intervals.
- To assess and compare the incidence of adverse effects associated with the use of herbal mouthwash and chlorhexidine.

- To determine whether the herbal mouthwash provides a clinically acceptable and well-tolerated alternative to chlorhexidine for routine oral hygiene management.

2. METHODOLOGY

The purpose of this randomised controlled study was to determine which herbal mouthwashes were most effective in avoiding gingivitis in adults and which ones were safest to use. A standardized approach to participant recruiting, uniform delivery of interventions, and trustworthy evaluation of therapeutic outcomes were all goals of the methodology's development.

2.1. Research Design

It was a randomized controlled experiment using a parallel-group design. Two groups, one using herbal mouthwash and the other using chlorhexidine, were randomly assigned to participants from three different dental institutes. Researchers used a single-blind design to ensure that no one could tell which groups the participants were in. Four weeks were the duration of the intervention.

2.2. Sample Details

In all, 120 adults with mild to moderate gingivitis, ranging in age from 18 to 45 years, were included in the study. Dental clinics that provide outpatient services were used to enroll participants. The study's inclusion criteria were a history of gum inflammation, the existence of 20 or more natural teeth, and the absence of periodontal treatment in the preceding six months. Exclusion criteria included a history of systemic illness, smoking, pregnancy, or the use of antibiotics or mouthwash within the past three months. Using computer-generated block randomization, participants were assigned at random.

2.3. Instruments and Materials Used

The herbal mouthwash contained Aloe vera, neem extract, and turmeric, prepared under standardized laboratory conditions. The control group received 0.12% chlorhexidine. Gingival health was assessed using:

- Gingival Index (Loe & Silness)
 - Plaque Index
 - Visual Analog Scale (VAS) for subjective adverse effects
- Sterile disposable probes, clinical examination kits, and standardized mouthwash bottles were utilized across all centers.

2.4. Procedure and Data Collection Methods

Prior to randomization, baseline evaluations were carried out. The recommended dosage of the assigned mouthwash was 10 ml, and participants were to use it twice a day, 30 seconds after cleaning their teeth. Weekly phone follow-ups and returned bottle volumes were used to monitor compliance.

Examining the patient at baseline, 2 weeks, and 4 weeks, calibrated examiners conducted clinical examinations. Forms for clinical assessments were already created and used to capture all data. During the course of the trial, any adverse events that occurred were recorded.

2.5. Data Analysis Techniques

The information was entered into SPSS (version 25) after coding. The demographic and clinical data were summarized using descriptive statistics. To assess changes within and between groups over time, we used paired t-tests and ANOVA for repeated measures. Statistical significance was determined by a p-value less than 0.05. Frequency distributions were used for the analysis of safety outcomes.

3. RESULTS

This chapter details the findings of a randomized clinical experiment that evaluated the safety and effectiveness of herbal mouthwashes in avoiding gingivitis over the course of four weeks. The trial was carried out at multiple centers. There were three time points in the data analysis for the Herbal Mouthwash Group and the Chlorhexidine Control Group: baseline, two weeks, and four weeks. Descriptive statistics, comparative analyses, and safety outcomes are the categories into which the findings are classified.

With 60 people in each group, a grand total of 120 people were registered. There were no discernible disparities in the gender or age distributions of the two groups as we started off.

Table 1. Descriptive Statistics of Participants at Baseline

Variable	Herbal Group (n=60)	Control Group (n=60)	p-value
Mean Age (years)	29.84 ± 6.12	30.21 ± 5.98	0.68
Gender (M/F)	28/32	30/30	0.71

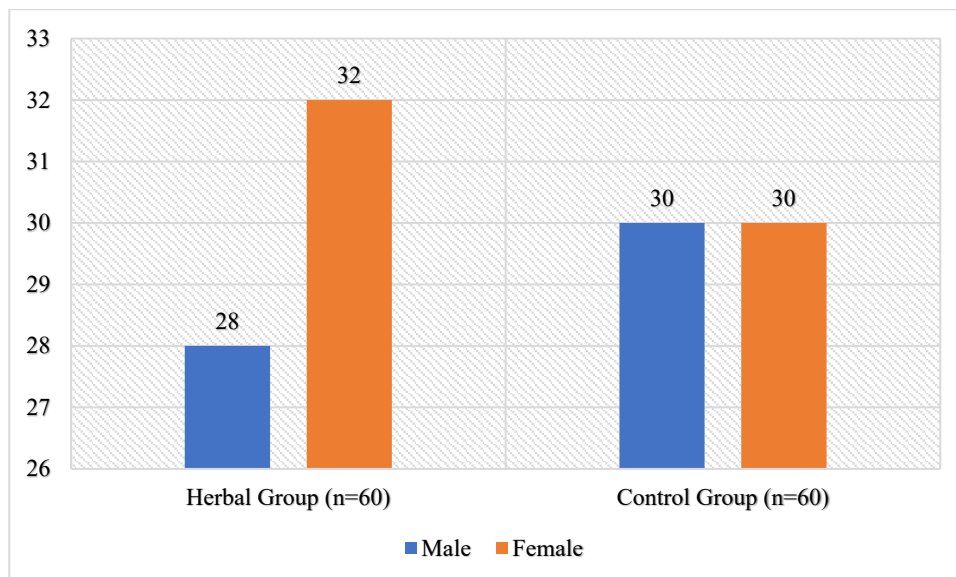


Figure 1: Visual Representation of Gender at Baseline

Table 1 shows that there were no statistically significant changes in the gender distribution or mean age between the control and herbal groups ($p > 0.05$). The results show that the two groups were

similar from the beginning, which means that the interventions were the main cause of the disparities in outcomes.

To assess the impact of the mouthwash treatments on gingival inflammation, the Gingival Index was assessed at baseline, 2 weeks, and 4 weeks. Below, you can see the means and standard deviations for every interval for both groups.

Table 2. Mean Gingival Index Scores at Baseline, 2 Weeks, and 4 Weeks

Time Interval	Herbal Group (Mean \pm SD)	Control Group (Mean \pm SD)
Baseline	1.92 \pm 0.28	1.94 \pm 0.31
2 Weeks	1.38 \pm 0.25	1.32 \pm 0.22
4 Weeks	0.92 \pm 0.20	0.89 \pm 0.18

Both groups' Gingival Index scores decreased throughout the course of the four weeks, as seen in Table 2. Although there was a noticeable improvement in both groups, the herbal mouthwash group showed comparable decreases to the chlorhexidine group, suggesting that it effectively controlled gingival inflammation.

The changes in dental plaque accumulation over time were evaluated by recording the Plaque Index scores at the same three periods. As seen in Table 3, the control group and the herbal group both had mean scores.

Table 3. Mean Plaque Index Scores at Baseline, 2 Weeks, and 4 Weeks

Time Interval	Herbal Group (Mean \pm SD)	Control Group (Mean \pm SD)
Baseline	2.01 \pm 0.33	2.04 \pm 0.30
2 Weeks	1.44 \pm 0.29	1.39 \pm 0.26
4 Weeks	0.97 \pm 0.23	0.90 \pm 0.21

Table 3 shows that both groups experienced a gradual decrease in plaque buildup. Both treatments reduced plaque significantly by week 4, with the herbal mouthwash doing almost as well as the chlorhexidine mouthwash.

The chlorhexidine group primarily experienced mild stains and changes in taste. The herbal group did not experience any serious side effects.

Table 4. Frequency of Adverse Events

Adverse Event	Herbal Group (n=60)	Control Group (n=60)
Mild Staining	2 (3.3%)	14 (23.3%)
Taste Alteration	1 (1.6%)	12 (20.0%)
Burning Sensation	0	3 (5.0%)

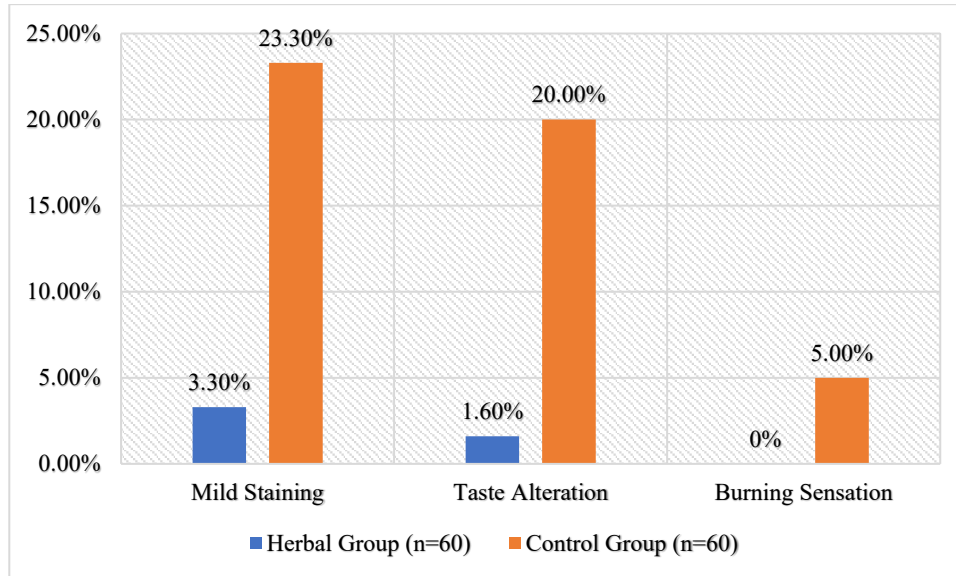


Figure 2: Visual Representation of Frequency of Adverse Events

Table 4 highlights that adverse events were considerably lower in the herbal group compared to the chlorhexidine group. Participants using chlorhexidine reported a higher incidence of mild staining and taste alteration, indicating that the herbal mouthwash was better tolerated overall.

3.1. Statistical Analysis

To evaluate changes in Gingival Index scores over time and between groups, a repeated measures ANOVA was performed. The results of the within-subjects tests are summarized in Table 5.

Table 5. Tests of Within-Subjects Effects (SPSS Output Format)

Source	Type III Sum of Squares	df	Mean Square	F	Sig.
Time	42.218	2	21.109	198.452	.000
Time × Group	1.543	2	0.772	7.254	.001
Error (Time)	12.648	238	0.053	—	—

Both groups saw a considerably noteworthy enhancement in gingival health as time progressed, as demonstrated in Table 5 ($p < 0.001$). Though both groups demonstrated significant decreases,

the minor difference in the rate of improvement between them is suggested by the significant Time \times Group interaction.

Alterations to the Plaque Index scores at each of the three evaluation points were examined using a comparable repeated measures ANOVA. Table 6 displays the statistical result for the impacts that occurred within the subjects.

Table 6. Tests of Within-Subjects Effects (SPSS Output Format)

Source	Type III Sum of Squares	df	Mean Square	F	Sig.
Time	39.502	2	19.751	181.623	.000
Time \times Group	2.004	2	1.002	9.214	.000
Error (Time)	12.942	238	0.054	—	—

Table 6 shows that both groups' plaque levels significantly decreased over time ($p < 0.001$). Although both treatments were successful in decreasing plaque buildup, the substantial interaction effect implies that the improvement patterns varied slightly between groups.

At week 4, the herbal and chlorhexidine groups' final Gingival Index and Plaque Index scores were compared using an independent samples t-test. Tabulated in Table 7 is the output formatted by SPSS.

Table 7. Independent Samples Test

Variable	Levene's Test for Equality of Variances (Sig.)	t	df	Sig. (2-tailed)	Mean Difference
Gingival Index (4 Weeks)	.381	1.12	118	.265	0.03
Plaque Index (4 Weeks)	.442	1.56	118	.121	0.07

The results in Table 7 indicate no statistically significant differences between the two groups at the 4-week mark ($p > 0.05$). This suggests that the herbal mouthwash was as effective as chlorhexidine in improving gingival and plaque outcomes by the end of the intervention period.

4. DISCUSSION

Using a 4-week intervention period, this randomized clinical research sought to assess the safety and effectiveness of herbal mouthwashes in avoiding gingivitis. The trial was conducted at multiple centers. Significant improvements in gingival health and decrease of plaque were observed with both the herbal formulation and chlorhexidine. Herbal mouthwash, on the other hand, has a better safety record, which bodes well for its future as an effective substitute for regular

dental care. Findings interpretation, links to previous research, limits, and future directions are all covered in this chapter.

4.1. Interpretation of Results

Statistical analysis revealed that at the end of the four weeks, both the herbal and chlorhexidine groups had significantly lower Gingival Index and Plaque Index scores. At the conclusion of the study, there was no statistically significant difference between the groups, which means that the herbal mouthwash had the same clinical effects as chlorhexidine. Also, the herbal group had much fewer side effects, which shows how much better it is tolerated, so it could be a good alternative, particularly for people who are allergic to chemical-based rinses. In conclusion, the results provide credence to the idea that herbal remedies might alleviate inflammation of the gums and plaque buildup without negatively impacting patient comfort.

4.2. Comparison of Existing Studies

Consistent with previous research showing that herbal and natural formulations are effective in gingivitis management, the current study's results support this approach. Our findings of equal effectiveness between the herbal and chlorhexidine groups are supported by Inchingolo et al. (2025)¹¹, who also found that natural mouthwashes produced clinical improvements similar to those of conventional chemical agents. The same decreases observed in both groups in our research are supported by Soesanto et al. (2023)¹², who also found that herbal mouthwashes were just as effective as chlorhexidine in reducing gingival inflammation and plaque. The randomized controlled trial conducted by Chiam et al. (2024)¹³ confirmed that mouthwashes made of natural enzymes significantly reduced plaque levels; this finding is in line with the gradual reduction of plaque observed in our herbal group. Our results of less side effects and better tolerance in the herbal group are consistent with those of Soodsakorn et al. (2025)¹⁴, who also found that their herbal mouthwash containing coconut oil was very safe and well-received by users. In addition, Balkrishna et al. (2024)¹⁵ highlighted the therapeutic benefits and safety of herbal medications in oral care in their clinical review, lending credence to the relevance and clinical validity of herbal-based therapies like the ones we tested. All things considered, the results of these research support the idea that herbal mouthwashes are a safer and more effective alternative to commercially available chemical formulations for promoting healthy gums.

4.3. Implication of Existing Studies

Consistent with and building upon prior research, the following are the results of this study:

- Gingival and plaque scores were found to decrease in correlation with the antioxidant, anti-inflammatory, and antibacterial characteristics of herbal extracts such turmeric, neem, and Aloe vera.
- Herbal mouthwashes and chlorhexidine have shown similar efficacy in multiple clinical trials, especially when it comes to the short-term treatment of gingivitis.
- Chlorhexidine has a history of negative consequences, including stains, changes in taste, and irritation of the mucosal surfaces; these findings corroborate the increased frequency of side effects in the control group.

- The present study's high tolerability is in line with previous research on the long-term use of natural formulations, and the trial adds to the growing body of evidence from multiple centers that these alternatives are safer and better for oral health.

4.4.Limitations of the Study

A randomized, multi-center design has its advantages, but it also has several drawbacks that must be considered:

- Long-term impacts or sustained compliance cannot be considered because the intervention period was limited to 4 weeks.
- Problems with the study's design include its reliance on self-reported compliance and returned bottle checks, which could lead to reporting bias, its inclusion of only mild to moderate gingivitis cases in the sample, and its exclusion of microbiological assessments in favor of two clinical indices, the Gingival Index and the Plaque Index.
- Participants' subjective assessments of treatment efficacy may have resulted from the study's single-blind design.

4.5.Suggestions for Future Work

In light of these deficiencies, we suggest the following areas for further study:

- Determine the herbal formulations' long-term safety, relapse rates, and maintained effectiveness through long-term follow-up trials.
- The clinical usefulness should be expanded by including instances of severe gingivitis or early periodontitis.
- Use microbiological testing to look for changes in the bacterial composition of the mouth.
Figure out which plant-based combinations work best by comparing various herbal formulas.
- To keep evaluation bias to a minimum and boost internal validity, use a double- or triple-blind approach.
- Determine whether the treatment is cost-effective, how satisfied patients are overall, and whether they find the taste acceptable.

5. CONCLUSION

Herbal mouthwashes were compared to chlorhexidine in this multi-center randomized clinical research to see whether one was more effective and safer for avoiding gingivitis. With fewer side effects and higher overall acceptability, the herbal formulation was found to be just as effective as the conventional medication in lowering inflammation of the gums and plaque buildup over a 4-week period. In normal oral hygiene management, our results indicate that herbal mouthwashes can be a good, patient-friendly substitute for rinses based on chemicals.

5.1.Summary of Key Findings

The following is a synopsis of the study's main points:

- Gingival Index and Plaque Index scores were significantly reduced throughout the research period by both chlorhexidine and the herbal mouthwash.

- The groups showed similar levels of effectiveness after 4 weeks, as there was no statistically significant difference between them.
- Less discoloration, altered taste, and discomfort were reported with the herbal mouthwash, indicating higher tolerability.
- The validity of result comparisons was supported by the fact that baseline demographic factors, such as age and gender, were comparable between groups.
- Participants were sufficiently compliant to allow for valid assessment of the intervention's efficacy.

5.2. Significance of the Study

As an alternative to chlorhexidine, this study lends credence to the idea that herbal mouthwashes can effectively and safely treat gingivitis. The results significantly add to preventative dental care practices, which are becoming more popular as patients seek out oral care solutions that are both natural and free of negative effects. In addition to enhancing long-term adherence and dental health outcomes, the data highlight that herbal formulations can deliver comparable therapeutic advantages while avoiding discomfort.

5.3. Recommendations

The study's results and their significance led to the following suggestions:

- For patients who are sensitive to chlorhexidine's side effects, consider using herbal mouthwashes as an alternative in your regular dental practice.
- Promote the use of herbal-based oral hygiene products by dental practitioners and urge them to inform patients about their benefits.
- Confirm the safety and efficacy of herbal formulations over the long term by conducting additional studies with longer follow-up times.
- Determine the most effective combinations for gingivitis control by investigating changes in herbal compositions.
- To have a better grasp of the mechanisms at work, future experiments should incorporate microbiological and biochemical characteristics.
- Broaden the age range and severity of periodontal disease included in the study population.
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