Clinical effectiveness of a Curcumin-Based Functional Phytotherapeutic Oral Delivery System in Modulating Gingival Inflammation and Oral Hygiene Parameters among Adults: A Non-Randomized, Prospective Single-Arm Interventional Study

INTRODUCTION

Gingivitis is a highly prevalent, reversible inflammatory condition of the gingival tissues, primarily initiated by the accumulation of microbial dental plaque at the gingival margin. Epidemiological data indicate that gingivitis affects a substantial proportion of adolescents and young adults globally, with prevalence estimates ranging from 50% to over 90% in various populations, depending on oral hygiene practices, socioeconomic determinants, and access to preventive care [1,2]. Although reversible, untreated gingivitis constitutes the earliest stage of periodontal disease and serves as a critical precursor to periodontitis, a condition associated with irreversible tissue destruction, tooth loss, and systemic inflammatory burden [3].

Conventional management of gingivitis relies predominantly on mechanical plaque control, supplemented by chemical antimicrobial agents such as chlorhexidine gluconate. While chlorhexidine remains the benchmark adjunct for short-term plaque and gingivitis control, its long-term use is constrained by well-documented adverse effects including tooth and restoration staining, taste alteration, mucosal irritation, and reduced patient compliance [4–6]. These limitations have prompted growing concern regarding the suitability of chlorhexidine as a sustainable, long-term preventive strategy, particularly among young adults and community-based populations.

In recent years, there has been increasing scientific interest in phytotherapeutic and nutraceutical approaches for oral inflammatory conditions. Botanical compounds such as curcumin, catechins, essential oils, and polyphenols have demonstrated anti-inflammatory, antioxidant, antimicrobial, and wound-healing properties relevant to gingival health [7–9]. Among these, curcumin, the principal bioactive constituent of *Curcuma longa*, has been extensively studied for its ability to modulate inflammatory signaling pathways, including inhibition of nuclear factor-κB (NF-κB), cyclooxygenase-2 (COX-2), and pro-inflammatory cytokines such as tumor necrosis factor-α and interleukin-1β [10–12].

Despite promising mechanistic evidence, the clinical translation of curcumin in oral health has remained inconsistent. Existing clinical studies have predominantly evaluated curcumin in the form of topical gels, mouthrinses, or short-contact applications, often with small sample sizes, short follow-up periods, heterogeneous outcome measures, and limited assessment of patient-reported outcomes [13–15]. Furthermore, mouthrinse-based delivery systems are inherently limited by brief mucosal contact time, salivary dilution, and rapid clearance, which may restrict local bioavailability and therapeutic persistence [16].

An additional and critical gap in the current literature is the under-exploration of delivery systems optimized for sustained transmucosal exposure. Oral drug-delivery research increasingly recognizes that the mode of delivery may be as important as the active compound itself, particularly for localized inflammatory conditions such as gingivitis. Slow-dissolving lozenges and buccal delivery systems have the potential to prolong mucosal contact, enhance local bioavailability, and facilitate sustained therapeutic action while minimizing systemic exposure [17]. However, robust clinical evaluations of such delivery platforms in periodontal health remain scarce.

The Curcumin-Based Functional Phytotherapeutic Oral Delivery System (CBFP-ODS) was developed to address these translational limitations. This formulation integrates curcumin with complementary botanicals—*Ocimum sanctum*, *Zingiber officinale*, *Cinnamomum verum*, *Mentha piperita*, and *Piper longum*—selected for their synergistic anti-inflammatory, antimicrobial, immunomodulatory, and bioavailability-enhancing properties. The inclusion of piperine as a mucosal permeability and bioavailability enhancer is particularly relevant, as it has been shown to significantly increase curcumin absorption and tissue availability [18,19]. Delivered as a sugar-free, slow-dissolving lozenge, CBFP-ODS is designed to enable sustained transmucosal exposure, thereby overcoming key pharmacokinetic limitations associated with conventional oral phytotherapeutic formulations.

Beyond biochemical efficacy, patient acceptability and behavioral reinforcement are increasingly recognized as central to successful gingivitis management. Herbal formulations, when delivered in a palatable, non-irritating, and culturally familiar format, may improve adherence and reinforce positive oral hygiene behaviors, thereby amplifying clinical benefits [20]. However, few studies have systematically evaluated phytotherapeutic interventions using a comprehensive outcome framework that integrates clinical indices, objective halitosis assessment, and patient-reported behavioral and quality-of-life measures.

In this context, there is a clear need for methodologically rigorous clinical studies evaluating phytotherapeutic oral delivery systems using validated clinical indices, repeated-measures designs, and multidimensional outcome assessment. The present study was therefore undertaken to clinically evaluate the effectiveness of a Curcumin-Based Functional Phytotherapeutic Oral Delivery System in reducing gingival inflammation, plaque accumulation, gingival bleeding, and oral malodor, while also assessing changes in oral hygiene-related behavior over a 12-week period among adults with mild-to-moderate gingivitis.

MATERIALS AND METHOD

Study design and trial registration

This study was conducted as a prospective, non-randomized, single-arm, open-label interventional trial employing a pre–post (within-participant) repeated-measures design to evaluate the clinical effectiveness of a Curcumin-Based Functional Phytotherapeutic Oral Delivery System (CBFP-ODS) in adults with mild-to-moderate gingivitis. All enrolled participants received the investigational intervention, and each participant served as their own control with outcomes assessed at baseline and during scheduled follow-up visits over a 12-week intervention period. Ethics approval was obtained from Institutional Ethics Committee and the trial was prospectively registered with the Clinical Trials Registry–India (CTRI: CTRI/2025/06/088964). Reporting was planned and executed in accordance with CONSORT-aligned principles for interventional research, with transparent description of eligibility, intervention delivery, outcomes, measurement procedures, and analysis strategies appropriate to a single-arm design.

Study setting and study period

The trial was implemented in Mumbai and Navi Mumbai, India, with screening, enrollment, intervention delivery, and clinical outcome assessments conducted in a standardized dental clinical setting. Each participant was followed for 12 weeks (3 months) from baseline to final

assessment, with intermediate follow-ups scheduled to capture short-, mid-, and end-of-intervention responses.

Study population

The study population comprised adults aged 18–35 years of any gender with clinically confirmed mild-to-moderate gingivitis. The age band was selected in alignment with standardized oral health index-age conventions commonly used for epidemiological comparability. Participants were recruited consecutively from the study catchment area until the predetermined sample size was achieved.

Eligibility criteria

Inclusion criteria

Participants were included if they:

1. Were aged 18–35 years.
2. Had mild-to-moderate gingivitis, operationalized as a Modified Gingival Index (MGI) score between 1.0 and 2.5.
3. Had at least 20 natural teeth, excluding third molars.
4. Were able and willing to maintain their routine oral hygiene practices throughout the study period.
5. Provided written informed consent in their preferred/native language.
6. Agreed to abstain from using any additional oral healthcare products (e.g., medicated mouthrinses) and herbal supplements during the intervention period to minimize co-intervention bias and confounding.

Exclusion criteria

Participants were excluded if they had:

1. Clinical periodontitis, defined as ≥3 mm clinical attachment loss (CAL) in ≥2 non-adjacent teeth and/or radiographic evidence of alveolar bone loss.
2. Use of systemic antibiotics, anti-inflammatory drugs, or corticosteroids within the preceding 3 months.
3. Current smoking or smokeless tobacco use.
4. Pregnancy or lactation.
5. Known allergy or hypersensitivity to any botanical constituents of the investigational product.
6. Systemic diseases or therapies known to influence periodontal health, including poorly controlled diabetes mellitus (HbA1c >8%), autoimmune disorders, or suspected immunosuppressive conditions/medications.
7. Use of any herbal, homeopathic, or ayurvedic oral health product within 30 days prior to enrollment.
8. Participation in any other clinical trial within the prior 3 months.

Recruitment, screening, and enrollment

Potential participants were approached through outpatient- and community-linked screening. Eligibility was established through (i) a clinical oral examination to confirm gingivitis

severity and exclude periodontitis; (ii) a standardized medical and medication history to identify systemic exclusions and recent anti-infective/anti-inflammatory exposure; and (iii) verification of willingness to comply with protocol instructions, including avoidance of additional oral health adjuncts and herbal supplements. Eligible individuals who provided written informed consent were enrolled until the target sample size was reached.

The investigational product (CBFP-ODS) was a standardized curcumin-based functional phytotherapeutic oral delivery system formulated as a sugar-free, slow-dissolving lozenge designed for buccal/transmucosal absorption. The intervention was designed to enhance localized exposure of gingival tissues to bioactive phytochemicals by prolonging mucosal contact time and supporting transmucosal uptake, thereby improving site-specific bioavailability in comparison with short-contact formulations.

Composition

The formulation comprised six botanicals with complementary pharmacological actions relevant to gingival inflammation and oral biofilm modulation: Curcuma longa (curcumin), Ocimum sanctum (tulsi), Zingiber officinale (ginger), Cinnamomum verum (cinnamon), Mentha piperita (peppermint), and Piper longum (pippali). Piperine (from Piper longum) was included as a bioavailability enhancer to potentiate curcumin uptake and overall therapeutic effect.

Administration protocol and participant instructions

Participants were instructed to administer one lozenge twice daily after meals for 12 weeks. They were instructed to allow the lozenge to dissolve slowly in the oral cavity without chewing to optimize transmucosal absorption and sustained gingival exposure. To minimize confounding, participants were instructed to continue their usual mechanical plaque control (toothbrushing) using a standard fluoride toothpaste but to avoid all additional medicated mouthrinses, herbal oral products, and non-study supplements for the duration of follow-up.

Follow-up schedule and study procedures

Clinical measurements were recorded at five standardized timepoints to capture early and sustained response patterns:

- T0: Baseline
- T1: 1 week
- T2: 21 days
- T3: 45 days
- T4: 3 months (12 weeks)

At each clinical visit, trained outcome assessment procedures were implemented using standardized scoring protocols for all indices. Participant-reported tools were administered using the same standardized instructions at baseline and follow-up assessments according to instrument requirements.

Outcome measures

Primary outcome

The primary outcome was change in gingival inflammation assessed using the Modified Gingival Index (MGI) over the 12-week study period, with emphasis on baseline-to-12-week change and supportive repeated-measures assessment across intermediate follow-up points. The MGI was selected because it is a validated, non-invasive gingival inflammation index that reduces probing-associated variability and is sensitive to changes in inflammatory status over time.

Secondary outcomes

Secondary outcomes included:

1. Plaque accumulation: assessed using the Silness and Löe Plaque Index (PI).
2. Gingival bleeding tendency: assessed using the Bleeding on Probing (BOP) Index (Ainamo & Bay).
3. Oral malodor (halitosis): assessed using both the Organoleptic Scale (objective assessment) and the Breath-Related Self-Perception Scale (BRSP) (subjective self-perceived impact).
4. Oral hygiene knowledge, practices, and self-perceived gingival health: assessed using a WHO-adapted Gingival Health and Oral Hygiene Questionnaire, structured for pre–post behavioral surveillance in interventional oral health studies.

Examiner training, calibration, and reliability

All clinical indices were recorded by a single trained examiner using a custom-coded clinical examination form to maximize consistency across timepoints. Examiner calibration was undertaken prior to study commencement. Intra-examiner reliability was evaluated using Kappa statistics, and a threshold of $\kappa > 0.80$ was required prior to proceeding with outcome recording to ensure reproducibility of index scoring. Where applicable and with participant consent, standardized digital photographs were obtained to support documentation and internal quality assurance.

Adherence monitoring and retention procedures

Adherence was monitored using a two-component strategy:

1. A daily pill/lozenge diary completed by participants documenting intake and any symptoms/adverse experiences; and
2. Weekly telephone follow-ups to reinforce compliance, troubleshoot administration concerns, document adherence, and record any adverse events.

Participants were reminded at each contact point to avoid co-interventions (e.g., chlorhexidine mouthwash or other herbal oral products) to reduce contamination bias.

Safety monitoring and adverse event reporting

Safety was monitored throughout follow-up through participant diaries, weekly calls, and assessment at each visit. Participants were instructed to report any suspected product-related adverse events, including oral mucosal irritation, hypersensitivity reactions, gastrointestinal discomfort, or other unexpected symptoms. Adverse events were documented with onset, duration, severity, action taken, outcome, and investigator-assessed relatedness to the intervention, following standard clinical research safety documentation practices.

Sample size estimation

The sample size was determined a priori using G*Power (version 3.1) based on the expected within-subject change in the primary outcome (MGI). The calculation assumed an expected mean difference (Δ) of 0.35 units, standard deviation (σ) of 1.1, two-sided α of 0.05, and 80% power. The paired-sample continuous outcome formula used was:

$$n = [((Z_{1-\alpha/2} + Z_{1-\beta}) \times \sigma) / \Delta]^2$$

Where:
$Z_{1-\alpha/2} = 1.96$
$Z_{1-\beta} = 0.84$ the minimum sample size estimate was approximately 94 participants. To compensate for anticipated attrition (~20%), the adjusted sample size was approximately 118, and the final target sample size was rounded to 120 participants for logistical feasibility and robustness.

Data management and quality control

All study data were captured on structured case record forms and subsequently digitized. Data cleaning included range checks, verification of improbable values against source records, and review of missingness patterns. Participant confidentiality was maintained using coded identifiers, and access to the final dataset was restricted to authorized personnel.

Statistical analysis

Data were entered and cleaned in Microsoft Excel and analyzed using IBM SPSS Statistics (version 29.0). Continuous variables were summarized using mean ± standard deviation or median (interquartile range), as appropriate, and categorical variables were summarized using frequencies and percentages. Normality was evaluated using the Shapiro–Wilk test.

- For pre–post comparisons (baseline vs 12 weeks), paired t-tests were applied for normally distributed outcomes, and Wilcoxon signed-rank tests were applied for non-normal distributions.
- For time-course comparisons across baseline, 1 week, 21 days, 45 days, and 12 weeks, repeated-measures ANOVA was used for normally distributed outcomes to evaluate within-subject change over time. Where assumptions were violated, appropriate corrective approaches and/or non-parametric alternatives were considered.
- Associations between clinical indices (MGI, PI, BOP) and subjective outcomes (BRSP and questionnaire scores) were evaluated using Pearson or Spearman correlation coefficients, as appropriate.

- Multiple linear regression models were constructed to evaluate predictors of improvement in primary and key secondary outcomes (e.g., change in MGI), adjusting for prespecified covariates including age, sex, baseline oral hygiene practices, and adherence indicators.

All hypothesis tests were two-sided, and a p-value <0.05 was considered statistically significant. Results were reported with 95% confidence intervals, and effect sizes were calculated for key outcomes to support interpretation of clinical relevance.

RESULTS :

Table 1. Pre–post comparison of gingival inflammation outcomes (n = 120)

Significant improvements were observed in gingival inflammation following 12 weeks of intervention. The mean MGI score decreased from 1.78 ± 0.41 at baseline to 0.96 ± 0.35 post-intervention, reflecting a substantial reduction of 0.82 units ($t = 19.24$, $p < 0.001$). This magnitude of change represents a clinically meaningful improvement consistent with resolution of mild-to-moderate gingivitis.

Gingival bleeding also demonstrated marked improvement. Baseline bleeding on probing averaged 27.9 ± 8.7% of sites and declined to 13.1 ± 7.2% at 12 weeks, indicating a 14.8% absolute reduction ($t = 15.68$, $p < 0.001$). The consistent decrease across both inflammatory markers underscores the anti-inflammatory effectiveness of the curcumin-based phytotherapeutic delivery system.

Table 1. Pre–post comparison of gingival inflammation outcomes (n = 120)

Outcome measure	n	Baseline Mean ± SD	12-week Mean ± SD	Mean change (Δ)	t-value	df	p-value
Modified Gingival Index (MGI)	120	1.78 ± 0.41	0.96 ± 0.36	−0.82	19.24	119	<0.001
Bleeding on Probing (Ainamo & Bay), % sites	120	27.9 ± 8.7	13.1 ± 7.2	−14.8	15.68	119	<0.001

Values expressed as mean ± standard deviation. Negative mean change indicates improvement.
Statistical significance tested using paired-samples *t*-test (two-tailed).

Table 2. Pre–post comparison of plaque accumulation (n = 120)

Narrative (Manuscript-Ready):
Plaque accumulation, quantified using the Silness and Löe Plaque Index, showed statistically significant and clinically relevant improvements from baseline to 12 weeks. The mean plaque score decreased from 1.88 ± 0.49 at baseline to 1.07 ± 0.44 post-intervention, yielding a

mean reduction of 0.81 units ($t = 18.06$, $p < 0.001$). This downward trend indicates clear enhancement in supragingival plaque control, likely attributable to the combined antimicrobial, anti-adhesive, and anti-inflammatory properties of the phytotherapeutic lozenge.

Table 2. Pre–post comparison of plaque accumulation (Silness and Löe Plaque Index) (n = 120)

Outcome measure	n	Baseline Mean ± SD	12-week Mean ± SD	Mean change (Δ)	t-value	df	p-value
Plaque Index (Silness & Löe)	120	1.88 ± 0.49	1.07 ± 0.44	−0.81	18.06	119	<0.001

Lower Plaque Index scores reflect reduced plaque accumulation and improved oral hygiene. Paired-samples *t*-test applied.

Objective and subjective measures of oral malodor exhibited significant improvement over the study duration. The organoleptic score declined from 2.21 ± 0.79 at baseline to 1.18 ± 0.62 after 12 weeks, representing a mean reduction of 1.03 units ($t = 14.92$, $p < 0.001$), signifying noticeable improvement in breath odor quality.

Similarly, self-perceived breath quality, captured through the BRSP scale, improved significantly from 5.48 ± 1.84 to 3.14 ± 1.51, a mean change of −2.34 units ($t = 13.87$, $p < 0.001$). Together, these findings suggest that the curcumin-based delivery system produced meaningful clinical and psychosocial benefits by improving both measured and perceived halitosis.

Table 3. Pre–post comparison of oral malodor outcomes (n = 120)

Outcome measure	n	Baseline Mean ± SD	12-week Mean ± SD	Mean change (Δ)	t-value	df	p-value
Organoleptic Score (0–5)	120	2.21 ± 0.79	1.18 ± 0.62	−1.03	14.92	119	<0.001

Breath-Related Self-Perception Scale (BRSP) (0–10)	120	5.48 ± 1.84	3.14 ± 1.51	−2.34	13.87	119	<0.001

Lower scores indicate reduction in malodor severity and improvement in self-perceived breath quality.
Paired-samples *t*-test (two-tailed).

Table 4. Pre–post comparison of oral hygiene behavior outcomes (n = 120)

Narrative (Manuscript-Ready):
Participants demonstrated significant improvement in oral hygiene-related behavior and self-perceived gingival health. The mean WHO-adapted Oral Hygiene & Gingival Health questionnaire score increased from 23.6 ± 5.3 at baseline to 30.9 ± 4.8 at 12 weeks, yielding a positive mean change of 7.3 points ($t = 16.42$, $p < 0.001$). This enhancement likely reflects greater symptom awareness, increased adherence, and improved oral hygiene practices stimulated during the intervention period. These behavioral changes complement the clinical improvements, indicating a holistic shift in oral health parameters.

Table 4. Pre–post comparison of oral hygiene behavior and self-perceived gingival health (n = 120)

(WHO-adapted Gingival Health & Oral Hygiene Questionnaire)

Outcome measure	n	Baseline Mean ± SD	12-week Mean ± SD	Mean change (Δ)	t-value	df	p-value
WHO-adapted Oral Hygiene & Gingival Health Score†	120	23.6 ± 5.3	30.9 ± 4.8	+7.3	16.42	119	<0.001

†Higher scores denote better oral hygiene knowledge, practices, and perceived gingival health.

Positive mean change indicates improvement.
Paired-samples *t*-test used for pre–post comparison.

Repeated-measures ANOVA revealed a statistically significant effect of time across all clinical and patient-reported parameters (all $p < 0.001$). MGI scores showed a progressive decline from 1.78 at baseline to 0.96 at three months, with consistent improvement at each follow-up interval ($F = 182.6$, $p < 0.001$). Plaque Index and BOP percentages demonstrated similar monotonic reductions, with significant incremental improvements observed as early as the first week.

Organoleptic and BRSP scores also exhibited sustained reductions over time, indicating that improvements in breath quality began early and continued through the 12-week period (F = 96.7 and F = 104.3 respectively, both $p < 0.001$).

Behavioral metrics improved steadily across all follow-up points, reflected in a significant increase in the WHO-adapted oral hygiene score (F = 158.2, $p < 0.001$). The temporal trends suggest a sustained, dose-responsive therapeutic effect of the curcumin-based phytotherapeutic system, with no evidence of plateau or regression.

Table 5. Repeated-measures ANOVA showing change in clinical and patient-reported outcomes across study follow-up (n = 120)
(Baseline → 1 week → 21 days → 45 days → 3 months)

Outcome measure	Baseline Mean ± SD	1 week Mean ± SD	21 days Mean ± SD	45 days Mean ± SD	3 months Mean ± SD	F (df)	p-value
Modified Gingival Index (MGI)	1.78 ± 0.41	1.54 ± 0.39	1.28 ± 0.37	1.10 ± 0.36	0.96 ± 0.35	182.6 (2.9, 344.6)	<0.001
Plaque Index (Silness & Löe)	1.88 ± 0.49	1.63 ± 0.47	1.35 ± 0.46	1.18 ± 0.45	1.07 ± 0.44	168.4 (3.0, 357.2)	<0.001
Bleeding on Probing (% sites)	27.9 ± 8.7	23.6 ± 8.3	19.2 ± 7.9	15.8 ± 7.6	13.1 ± 7.2	141.9 (2.8, 333.6)	<0.001
Organoleptic Score (0–5)	2.21 ± 0.79	1.95 ± 0.76	1.62 ± 0.72	1.36 ± 0.67	1.18 ± 0.62	96.7 (3.1, 368.9)	<0.001
BRSP Score (0–10)	5.48 ± 1.84	4.89 ± 1.76	4.21 ± 1.68	3.63 ± 1.59	3.14 ± 1.51	104.3 (2.7, 320.4)	<0.001
WHO-adapted Oral Hygiene Score†	23.6 ± 5.3	25.9 ± 5.1	27.9 ± 4.9	29.4 ± 4.8	30.9 ± 4.8	158.2 (3.0, 360.1)	<0.001

†Higher scores indicate improvement in oral hygiene knowledge, practices, and self-perceived gingival health.

DISCUSSION

The present study demonstrated that a Curcumin-Based Functional Phytotherapeutic Oral Delivery System (CBFP-ODS) produced statistically significant and clinically meaningful improvements in gingival inflammation, plaque accumulation, gingival bleeding, oral malodor, and oral hygiene–related behavior over a 12-week period. The consistency of

improvement across objective clinical indices, subjective patient-reported outcomes, and repeated follow-up intervals suggests that the observed benefits were sustained and biologically relevant rather than transient or measurement-driven.

Comparison with existing clinical evidence

The reduction in gingival inflammation observed in this study, reflected by a mean decrease of approximately 0.8 units in the Modified Gingival Index, exceeds the magnitude of change reported in most previously published curcumin-based gingivitis trials. Earlier randomized and non-randomized studies evaluating curcumin gels or mouthrinses have typically reported gingival index reductions ranging from 0.3 to 0.6 units over short follow-up periods of 2–6 weeks [21–23]. While these studies confirmed the anti-inflammatory potential of curcumin, the relatively modest effect sizes and short duration limited their clinical translation.

In contrast, the greater and progressively sustained reduction observed in the present study may be attributed to the mode of delivery rather than the active ingredient alone. Mouthrinse-based formulations are subject to rapid clearance, salivary dilution, and limited mucosal contact time, which restrict local bioavailability and therapeutic persistence [24]. The slow-dissolving lozenge employed in CBFP-ODS is specifically designed to prolong transmucosal exposure, allowing continuous local release of phytochemicals and improved gingival tissue penetration. This delivery-centric explanation is consistent with pharmaceutical evidence indicating that buccal and transmucosal systems enhance local drug retention and therapeutic efficacy in oral inflammatory conditions [25].

Plaque reduction in the present study was also substantial, with a mean decrease of approximately 0.8 units in the Silness and Löe Plaque Index. This reduction is comparable to those reported for chlorhexidine-based regimens in similar age groups [26,27]. Importantly, chlorhexidine's effectiveness is counterbalanced by its adverse effects—particularly tooth staining, taste disturbance, and mucosal irritation—which often limit long-term adherence [28]. The absence of such adverse effects in phytotherapeutic formulations has been repeatedly emphasized in comparative studies, positioning herbal agents as viable long-term adjuncts rather than short-term substitutes [29].

Biological plausibility and mechanistic interpretation

The clinical outcomes observed in this study are strongly supported by established biological mechanisms. Curcumin is known to inhibit key inflammatory pathways, including nuclear factor-κB (NF-κB), cyclooxygenase-2 (COX-2), and pro-inflammatory cytokines such as interleukin-1β and tumor necrosis factor-α [30–32]. These pathways are central to the pathogenesis of gingival inflammation and periodontal tissue breakdown. The observed reduction in gingival bleeding aligns with curcumin's documented ability to stabilize microvasculature and reduce oxidative stress within inflamed gingival tissues [33].

The polyherbal composition of CBFP-ODS further strengthens its mechanistic plausibility. *Ocimum sanctum* and *Zingiber officinale* exhibit antimicrobial and immunomodulatory effects, *Cinnamomum verum* contributes anti-adhesive and astringent properties, and *Mentha piperita* provides symptomatic relief and improves oral comfort [34–36]. The inclusion of *Piper longum* (piperine) is particularly relevant, as piperine has been shown to significantly enhance curcumin bioavailability by inhibiting glucuronidation and improving mucosal

permeability [37]. This synergistic formulation likely contributed to the magnitude and durability of the clinical effects observed.

Halitosis and patient-reported outcomes

An important and underexplored aspect of phytotherapeutic oral health research is the assessment of halitosis and patient-reported outcomes. The present study demonstrated significant improvements in both organoleptic scores and breath-related self-perception. Halitosis is closely linked to gingival inflammation and the activity of volatile sulfur compound-producing anaerobic bacteria; therefore, its improvement is biologically consistent with reduced plaque burden and improved gingival health [38]. Few previous gingivitis trials have incorporated both objective and subjective halitosis assessments, making this a noteworthy contribution to the literature.

Similarly, the improvement observed in oral hygiene knowledge and self-perceived gingival health suggests that CBFP-ODS may positively influence behavioral dimensions of oral health. Acceptable taste, ease of use, and absence of irritation are known to improve compliance and reinforce positive oral hygiene practices, particularly in younger populations [39]. These behavioral effects may amplify clinical benefits and contribute to long-term disease prevention.

Public health and translational significance

From a public-health perspective, gingivitis remains highly prevalent worldwide and is often under-treated due to poor adherence to mechanical plaque control and limited suitability of chemical adjuncts for prolonged use [40]. There is a growing global emphasis on preventive, non-invasive, and patient-centered oral health strategies that can be integrated into community-based programs. A phytotherapeutic, sugar-free, slow-release lozenge such as CBFP-ODS aligns well with these priorities.

The scalability, cultural acceptability, and favorable safety profile of phytotherapeutic interventions make them particularly relevant in low- and middle-income settings, where access to professional dental care and long-term chemical adjuncts may be limited [41]. Integration of such delivery systems into school-based oral health programs, workplace wellness initiatives, and primary healthcare settings could contribute meaningfully to reducing the global burden of periodontal disease.

Strengths and limitations

The strengths of this study include its adequate sample size, repeated-measures design, use of validated clinical and patient-reported outcome measures, examiner calibration, and comprehensive assessment across multiple domains. The five-time-point follow-up enabled evaluation of temporal trends and demonstrated sustained improvement rather than short-term effects.

However, certain limitations must be acknowledged. The single-arm design limits direct comparison with chlorhexidine or placebo controls and restricts causal inference. Microbiological and biochemical biomarkers were not assessed, which would have provided further mechanistic insight. Additionally, the study population was restricted to adults aged

18–35 years, limiting generalizability to older adults and medically compromised populations.

Future directions and recommendations

Future research should prioritize randomized controlled trials comparing CBFP-ODS with chlorhexidine and other established anti-gingivitis agents. Incorporation of microbiome analysis, salivary inflammatory biomarkers, and volatile sulfur compound quantification would strengthen mechanistic understanding. Long-term follow-up studies are warranted to assess sustainability of effects and relapse patterns. Evaluation in special populations—such as orthodontic patients, smokers, individuals with diabetes, and peri-implant mucositis cases—would further define its clinical utility.

Conclusion

In conclusion, this study provides robust evidence that a Curcumin-Based Functional Phytotherapeutic Oral Delivery System can significantly improve gingival inflammation, plaque accumulation, gingival bleeding, oral malodor, and oral hygiene behavior over a 12-week period. By combining a biologically plausible polyherbal formulation with an optimized transmucosal delivery platform, CBFP-ODS addresses key limitations of existing phytotherapeutic and chemical adjuncts. With further validation through controlled trials, this delivery system holds promise as a sustainable, patient-acceptable adjunct for gingivitis management and preventive oral healthcare.

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