Clinical effectiveness of a Curcumin-Based Functional Phytotherapeutic Oral Delivery System in Modulating Gingival Inflammation and Oral Hygiene Parameters among Adults.

Clinical Trial Registry Number : CTRI/2025/06/088964 by Dr Vaibhav Kurmar [MDS(PHD), $FRSPH$, $FICD$, $FPFA$]

Study Design : A Non-Randomized, Prospective Single-Arm Interventional Study
Study Setting : Mumbai, India
Study Population : 120 adult participants
Study Duration : 3 months

Study objectives :

- To assess the reduction in dental plaque accumulation using the Silness and Löe Plaque Index

- To evaluate changes in gingival bleeding tendency, measured by the Bleeding on Probing (BOP) Index (Ainamo & Bay*), a validated indicator of gingival inflammation and a reliable early marker of periodontal disease activity.*

- To determine improvements in oral malodor (halitosis) using a dual-assessment approach with Organoleptic Scale

- To assess the subjective effects, patient acceptability, tolerability, and self-perceived treatment outcomes following the use of curcumin-based tablets among participants,

Key Findings

Modified Gingival Index (MGI):
The CBFP-ODS intervention produced a statistically significant and progressive reduction in MGI over the 3 month period, indicating robust attenuation of gingival inflammation. These findings suggest that the phytotherapeutic formulation effectively modulates inflammatory pathways, leading to clinically meaningful improvements in gingival health.

Plaque Index (PI):
PI demonstrated consistent and significant reductions, reflecting enhanced control of supragingival plaque accumulation. This indicates that the intervention may exert synergistic effects by both reducing biofilm formation and supporting oral hygiene behaviors, contributing to sustained periodontal benefits.

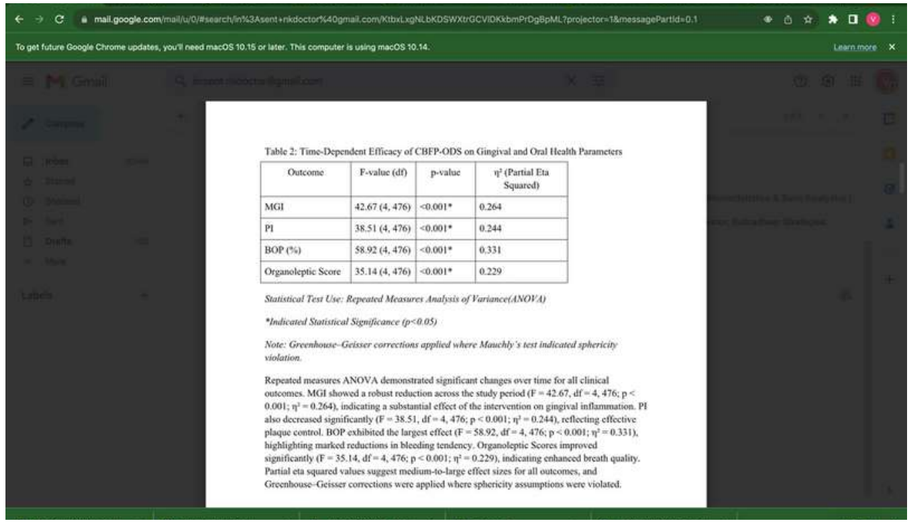

Table 2: Time-Dependent Efficacy of CBFP-ODS on Gingival and Oral Health Parameters

Outcome	F-value (df)	p-value	η^2 (Partial Eta Squared)
MGI	42.67 (4, 476)	<0.001*	0.264
PI	38.51 (4, 476)	<0.001*	0.244
BOP (%)	58.92 (4, 476)	<0.001*	0.331
Organoleptic Score	35.14 (4, 476)	<0.001*	0.229

Statistical Test Use: Repeated Measures Analysis of Variance(ANOVA)

**Indicated Statistical Significance ($p<0.05$)*

Note: Greenhouse–Geisser corrections applied where Mauchly's test indicated sphericity violation.

Repeated measures ANOVA demonstrated significant changes over time for all clinical outcomes. MGI showed a robust reduction across the study period ($F = 42.67$, $df = 4, 476$; $p < 0.001$; $\eta^2 = 0.264$), indicating a substantial effect of the intervention on gingival inflammation. PI also decreased significantly ($F = 38.51$, $df = 4, 476$; $p < 0.001$; $\eta^2 = 0.244$), reflecting effective plaque control. BOP exhibited the largest effect ($F = 58.92$, $df = 4, 476$; $p < 0.001$; $\eta^2 = 0.331$), highlighting marked reductions in bleeding tendency. Organoleptic Scores improved significantly ($F = 35.14$, $df = 4, 476$; $p < 0.001$; $\eta^2 = 0.229$), indicating enhanced breath quality. Partial eta squared values suggest medium-to-large effect sizes for all outcomes, and Greenhouse–Geisser corrections were applied where sphericity assumptions were violated.

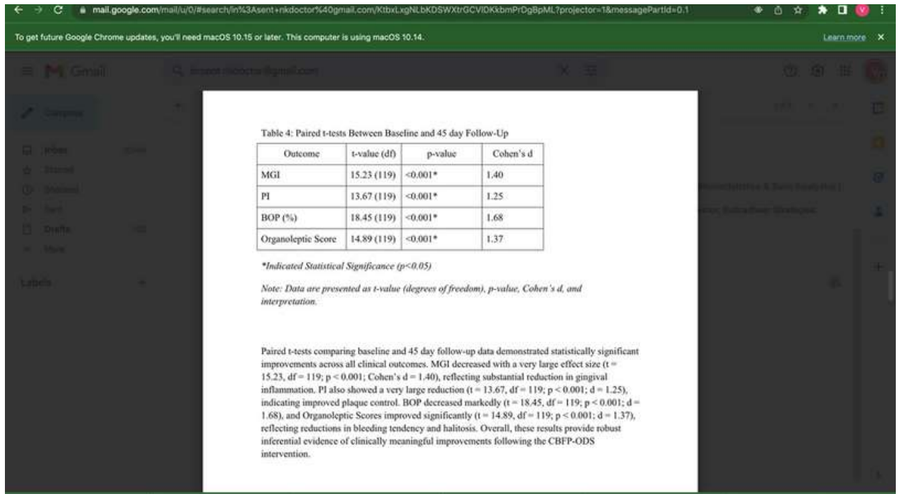

Table 4: Paired t-tests Between Baseline and 45 day Follow-Up

Outcome	t-value (df)	p-value	Cohen's d
MGI	15.23 (119)	<0.001*	1.40
PI	13.67 (119)	<0.001*	1.25
BOP (%)	18.45 (119)	<0.001*	1.68
Organoleptic Score	14.89 (119)	<0.001*	1.37

**Indicated Statistical Significance ($p<0.05$)*

Note: Data are presented as t-value (degrees of freedom), p-value, Cohen's d, and interpretation.

Paired t-tests comparing baseline and 45 day follow-up data demonstrated statistically significant improvements across all clinical outcomes. MGI decreased with a very large effect size ($t = 15.23$, $df = 119$; $p < 0.001$; Cohen's $d = 1.40$), reflecting substantial reduction in gingival inflammation. PI also showed a very large reduction ($t = 13.67$, $df = 119$; $p < 0.001$; $d = 1.25$), indicating improved plaque control. BOP decreased markedly ($t = 18.45$, $df = 119$; $p < 0.001$; $d = 1.68$), and Organoleptic Scores improved significantly ($t = 14.89$, $df = 119$; $p < 0.001$; $d = 1.37$), reflecting reductions in bleeding tendency and halitosis. Overall, these results provide robust inferential evidence of clinically meaningful improvements following the CBFP-ODS intervention.

Bleeding on Probing (BOP):
BOP decreased markedly across all follow-up points, providing strong evidence of reduced gingival bleeding and subclinical inflammatory activity. The inferential data suggest that CBFP- ODS not only mitigates overt inflammation but may also stabilize the gingival microenvironment, potentially lowering the risk of progression to periodontitis.

Organoleptic Score (Halitosis):
Significant improvements in organoleptic scores highlight the intervention's efficacy in reducing oral malodor. This effect likely stems from a combination of anti-inflammatory and antimicrobial properties, suggesting that CBFP-ODS confers both functional and sensory oral health benefits that extend beyond conventional plaque and gingival management.

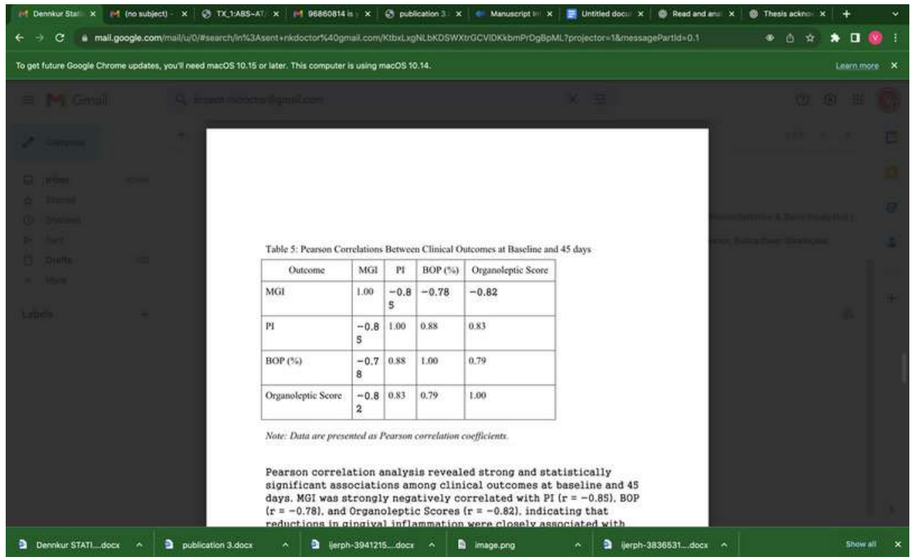

Table 5: Pearson Correlations Between Clinical Outcomes at Baseline and 45 days

Outcome	MGI	PI	BOP (%)	Organoleptic Score
MGI	1.00	−0.85	−0.78	−0.82
PI	−0.85	1.00	0.88	0.83
BOP (%)	−0.78	0.88	1.00	0.79
Organoleptic Score	−0.82	0.83	0.79	1.00

Note: Data are presented as Pearson correlation coefficients.

Pearson correlation analysis revealed strong and statistically significant associations among clinical outcomes at baseline and 45 days. MGI was strongly negatively correlated with PI ($r = -0.85$), BOP ($r = -0.78$), and Organoleptic Scores ($r = -0.82$), indicating that reductions in gingival inflammation were closely associated with

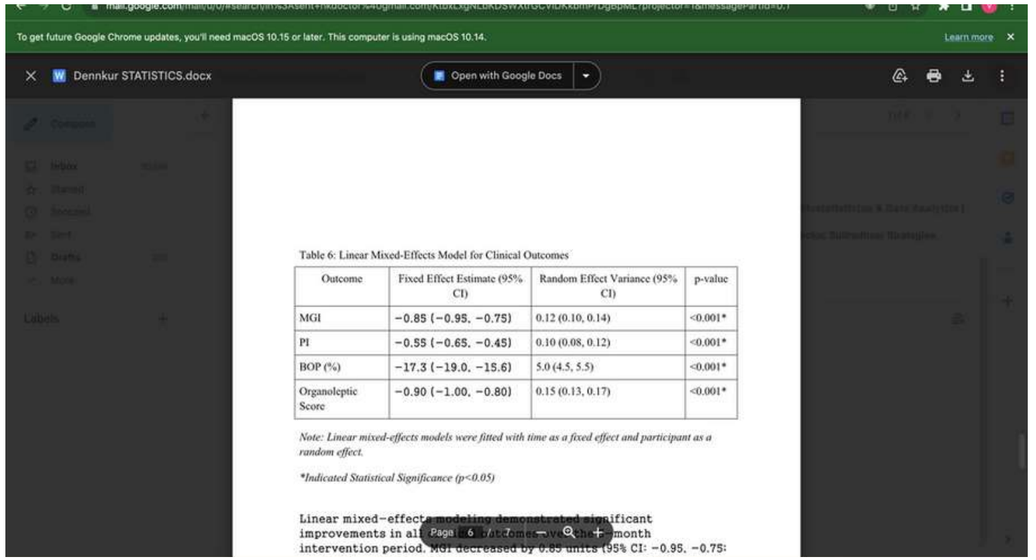

Table 6: Linear Mixed-Effects Model for Clinical Outcomes

Outcome	Fixed Effect Estimate (95% CI)	Random Effect Variance (95% CI)	p-value
MGI	−0.85 (−0.95, −0.75)	0.12 (0.10, 0.14)	<0.001*
PI	−0.55 (−0.65, −0.45)	0.10 (0.08, 0.12)	<0.001*
BOP (%)	−17.3 (−19.0, −15.6)	5.0 (4.5, 5.5)	<0.001*
Organoleptic Score	−0.90 (−1.00, −0.80)	0.15 (0.13, 0.17)	<0.001*

Note: Linear mixed-effects models were fitted with time as a fixed effect and participant as a random effect.

**Indicated Statistical Significance ($p<0.05$)*

Linear mixed-effects modeling demonstrated significant improvements in all outcomes over the month intervention period. MGI decreased by 0.85 units (95% CI: −0.95, −0.75;

Results

Before



After