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Original Research Article

Dia Smart Advantage: A Clinical Trial on Gummies/Candies for Diabetic Oral Wellbeing

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Abstract: ***Background*:** Diabetes mellitus is closely associated with a variety of oral complications, including periodontal disease, xerostomia, candidiasis, and delayed wound healing. Conventional management is often fragmented and poorly adhered to. This study evaluates the effectiveness of *HETAFU Dia Smart gummies/Candies*—a chewable supplement containing probiotics, essential oils, and micronutrients—as an adjunctive therapy for oral disease management in diabetic individuals. ***Methods*:** A total of 240 diabetic patients were enrolled and randomly assigned to 16 clusters (15 participants per cluster). Eight clusters received standard care (control), and eight received HETAFU Dia Smart gummies/Candies along with standard care (intervention). Clinical parameters were evaluated pre- and post-intervention across eight oral health domains: periodontal health, burning mouth syndrome, oral infections, mucosal lesions, salivary dysfunction, taste disturbance, post-endodontic pain, and wound healing. Outcomes included Gingival Index (GI), Plaque Index (PI), Clinical Attachment Loss (CAL), VAS scores, salivary flow rate, healing duration, and lesion measurements. ***Results*:** Post-intervention data revealed statistically significant improvements in the intervention group across all clusters. Notable reductions were observed in GI (1.07 ± 0.25 vs. 1.88 ± 0.56; $p \leq 0.001$), PI (1.06 ± 0.28 vs. 1.70 ± 0.44; $p \leq 0.001$), VAS for burning mouth (1.33 ± 1.18 vs. 5.20 ± 1.61; $p \leq 0.001$), and thrush area (2.13 ± 1.24 mm² vs. 9.93 ± 3.58 mm²; $p \leq 0.001$). Salivary flow increased (0.57 ± 0.14 vs. 0.33 ± 0.13 ml/min; $p \leq 0.001$), and healing time reduced significantly (5.07 ± 1.98 vs. 9.13 ± 2.50 days; $p \leq 0.001$). ***Conclusion*:** HETAFU Dia Smart gummies/Candies demonstrated significant adjunctive benefits in improving oral health outcomes among diabetic patients. Their easy-to-consume format, combined with multifactorial bioactive action, makes them a promising complementary approach in the integrated management of diabetes-associated oral conditions.

Keywords: Diabetes Mellitus, Oral Health, Probiotics, HETAFU Dia Smart Gummies/Candies, Xerostomia, Gingivitis, Wound Healing, Adjunctive Therapy, Clinical Trial.

INTRODUCTION

Oral health is an essential component of general well-being and significantly impacts systemic health, particularly in individuals with chronic conditions such as diabetes mellitus (DM). Diabetes, especially when poorly controlled, is associated with a range of oral manifestations, including gingivitis, periodontitis, burning mouth syndrome, xerostomia, candidiasis, taste dysfunction, and delayed wound healing [1–3]. The bidirectional relationship between periodontal disease and diabetes is well-established, with chronic hyperglycemia leading to increased inflammation, impaired immune response, and delayed tissue repair [4]. Conversely, untreated periodontal inflammation can adversely affect glycemic control by increasing systemic inflammatory burden [5].

Despite advances in dental care, managing oral conditions in diabetic patients remains challenging due to altered salivary composition, reduced flow, and compromised oral microbiota, which predispose these individuals to secondary infections and slow healing [6]. Furthermore, diabetic patients often experience decreased compliance with complex oral hygiene regimens due to comorbidities or age-related factors. This underscores the need for simple, non-invasive, and adjunctive oral care interventions that can be easily incorporated into their routine.

HETAFU Dia Smart gummies/Candies represent a novel therapeutic adjunct tailored for the diabetic population. These functional oral health supplements are formulated with low-glycemic

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sweeteners such as isomalt, maltitol, sorbitol, and stevia, making them safe for consumption without inducing blood glucose spikes [7]. Additionally, they contain prebiotics (FOS) and probiotics (*Bacillus coagulans*), which have shown beneficial effects in modulating oral microbiota, enhancing mucosal immunity, and reducing inflammation [8–9].

Essential oils included in the formulation offer antiseptic and anti-inflammatory properties, while acidity regulators help maintain oral pH balance and promote salivary stimulation [10]. The gummy format itself improves patient adherence, particularly in older adults or those with swallowing difficulties, and provides targeted delivery of therapeutic agents.

Clinical application of DIA SMART has shown promising outcomes across a spectrum of oral conditions commonly seen in diabetic patients. Early data suggest significant improvements in wound healing, salivary flow rate, reduction of lesion size, and symptomatic relief from burning mouth and taste dysfunction. When used alongside standard treatments such as oral prophylaxis, flap surgery, antibiotic regimens, and topical antifungal/anti-inflammatory gels, these gummies have demonstrated additive benefits with improved recovery timelines and patient-reported outcomes.

Thus, DIA SMART may serve as a safe, effective, and easy-to-use adjunct for improving oral health in diabetic individuals, supporting both local and systemic health outcomes.

METHODOLOGY

This was a multi-cluster, parallel-group, interventional study conducted to assess the adjunctive efficacy of *HETAFU Dia Smart gummies/Candies* in managing oral manifestations associated with Type 2 Diabetes Mellitus (T2DM). The study enrolled a total of 240 participants, all with confirmed T2DM (HbA1c ≥6.5%), who presented with at least one or more oral complications including gingivitis, burning mouth syndrome, candidiasis, xerostomia, or delayed wound healing.

The participants were divided into 16 clusters, each consisting of 15 patients. Cluster allocation was based on geographical or institutional grouping (e.g., patients attending different diabetic outpatient departments or dental clinics across multiple zones). Clusters were randomly assigned in a 1:1 ratio to either the Control Group (Standard Care) or the Test Group (Standard Care + HETAFU Dia Smart gummies/Candies) using a computer-generated randomization table to minimize selection bias.

Inclusion Criteria Were:

- Age above 18 years
- Diagnosed with T2DM for at least 1 year
- Presenting with at least one oral complaint: gingivitis, periodontitis, burning mouth, oral candidiasis, xerostomia, or delayed post-extraction healing
- Willing to comply with follow-up visits and gummy intake

Exclusion Criteria Included:

- Patients with Type 1 diabetes
- History of systemic immune disorders or current immunosuppressive therapy
- Undergoing chemotherapy/radiotherapy
- Known allergy to gummy ingredients
- Severe uncontrolled diabetes (HbA1c >11%)

All participants underwent a baseline clinical and oral examination, including assessment of:

- Gingival Index (Löe and Silness)
- Plaque Index
- Salivary flow rate (spitting method over 5 minutes)
- Visual Analogue Scale (VAS) for burning sensation and oral dryness
- Extent and severity of oral candidiasis (clinical scoring)
- Wound healing time (in patients with recent extractions)
- Taste dysfunction (questionnaire-based)
- HbA1c levels and duration of diabetes

The intervention group received *HETAFU Dia Smart gummies/Candies* (a formulation containing Prebiotic-FOS, sorbitol, xylitol, maltitol, probiotic - bacillus coagulans, essential oil cinnamon, curcumin, mint, clove , vitamins and minerals.), prescribed based on the specific oral condition. Dosages ranged from 2 to 3 gummies per day for 5 to 10 days (detailed in a treatment protocol table) and participants were instructed to chew each gummy thoroughly for at least one minute before swallowing. The control group received identical standard care without gummies, including oral prophylaxis, antibiotics, antifungal gel, or mouthwash as required.

All participants were followed up on Day 0 (baseline), Day 7, and Day 10. At each visit, clinical parameters were reassessed. Compliance to gummy intake was ensured via daily intake logs and periodic reminders. Any side effects or adverse reactions were documented. No patient dropped out of the study.

Data were collected in structured case record forms and digitized using Microsoft Excel. Statistical analysis was performed using SPSS version 25.0. Continuous variables were summarized using means and standard deviations, and categorical variables were described as frequencies and percentages. Inter-group comparisons (Control vs Test) were done using

independent t-tests depending on data normality. A p-value of <0.05 was considered statistically significant.

The study adhered to ethical guidelines laid down in the Declaration of Helsinki and received clearance from the Institutional Ethics Committee. All participants provided written informed consent.

Table 1: Dosage & Adjunct Therapy Guidelines for Clinical Use of Gummies

Condition	Dosage / Prescription	Adjunct Therapy
1. Gingivitis / Periodontitis / Alveolar Bone Loss	- 2 gummies/day for 2 days before oral prophylaxis or flap surgery - 3 gummies/day for 5 days post-surgery	Along with antibiotics
2. Burning Mouth Syndrome	2 gummies/day for 7 days	With mouthwash
3. Oral Infections (Thrush / Candidiasis)	3 gummies/day for 5 days	With antifungal gel application
4. Oral Mucosal Disorders (e.g., Lichen Planus)	2 gummies/day for 10 days	With topical gel
5. Salivary Dysfunction / Xerostomia (Dry Mouth)	3 gummies/day for 7 days	None specified
6. Taste Dysfunction	3 gummies/day for 5 days	None specified
7. Dental Caries (Post-RCT)	3 gummies/day for 5 days	With antibiotics
8. Delayed Wound Healing Post-Extraction	3 gummies/day for 10 days	With antibiotics and mouthwash

Table 2: Dia Smart Cluster-wise Oral Health Indices

S. No.	Oral Health Condition / Cluster	Suggested Indices for Evaluation
1	Gingivitis / Periodontitis / Alveolar Bone Loss	- Gingival Index (GI) - Plaque Index (PI) - Clinical Attachment Loss (CAL)
2	Burning Mouth Syndrome	- Visual Analogue Scale (VAS) for burning
3	Oral Infections (Thrush / Candidiasis)	- Lesion Area (mm^2) - Clinical Assessment Score - VAS for discomfort
4	Oral Mucosal Disorders (e.g., Lichen Planus)	- Mucositis Grading Scale - Lesion Area (mm^2)
5	Salivary Dysfunction / Xerostomia	- Salivary Flow Rate (ml/min) - Subjective Dryness Score
6	Taste Dysfunction	- VAS for Taste Loss
7	Dental Caries (Post-RCT recovery)	- Schiff Cold Air Sensitivity Scale
8	Delayed Wound Healing Post-Extraction	- Healing Time (Days)

RESULTS

The present study evaluated the effectiveness of *HETAFU Dia Smart gummies/Candies* as an adjunctive intervention in the management of oral manifestations among individuals with Type 2 Diabetes Mellitus (T2DM). A total of 240 participants were enrolled and equally distributed into 16 clusters, with 15 patients per cluster. Clusters were randomized into two groups: the Test Group, which received HETAFU Dia Smart gummies/Candies along with standard care, and the Control Group, which received standard care alone. Baseline characteristics such as age, gender, duration of diabetes, glycemic control (HbA1c), and type of oral lesions were comparable between the two groups, ensuring initial homogeneity. Clinical assessments were conducted at baseline, 7 days, and 14 days post-intervention. The following results highlight changes in oral symptoms, lesion resolution, salivary flow rate, and subjective patient-reported outcomes across both groups.

Table 3: Baseline Comparison with Cluster Classification

Parameter	Group 1 Mean ± SD	Group 2 Mean ± SD	Mean Diff.	p-value	Significant?	Oral Health Cluster
GI_Pre (Gingival Index)	1.94 ± 0.28	2.17 ± 0.33	-0.22	0.057	✕ (NS)	Gingivitis / Periodontitis / Bone Loss
PI_Pre (Plaque Index)	2.05 ± 0.29	2.10 ± 0.30	-0.05	0.642	✕ (NS)	
CAL_Pre (Attachment Loss)	4.06 ± 0.54	3.77 ± 0.59	+0.29	0.171	✕ (NS)	
VAS_Burning_Pre	6.93 ± 0.88	7.13 ± 0.83	-0.20	0.529	✕ (NS)	Burning Mouth Syndrome

Thrush_Area_Pre (mm²)	27.73 ± 3.96	25.33 ± 4.30	+2.40	0.123	✕ (NS)	Oral Infections (Thrush / Candidiasis)
Thrush_Score_Pre	3.20 ± 0.86	2.80 ± 0.78	+0.40	0.192	✕ (NS)	
Thrush_VAS_Pre	6.20 ± 0.78	6.00 ± 0.85	+0.20	0.505	✕ (NS)	
Mucositis_Pre	1.67 ± 0.49	1.53 ± 0.52	+0.13	0.473	✕ (NS)	Oral Mucosal Disorders (e.g., Lichen Planus)
Lesion_Area_Pre (mm²)	22.93 ± 4.38	23.67 ± 3.62	-0.73	0.621	✕ (NS)	
Salivary_Flow_Pre (ml/min)	0.36 ± 0.07	0.35 ± 0.08	+≤0.0017	0.981	✕ (NS)	Salivary Dysfunction / Xerostomia
Dryness_Score_Pre	7.27 ± 0.70	6.60 ± 0.83	+0.67	0.25	✕ (NS)	
Taste_VAS_Pre	7.13 ± 0.92	7.07 ± 0.88	+0.07	0.841	✕ (NS)	Taste Dysfunction
Schiff_Pre (Sensitivity)	2.47 ± 0.52	2.53 ± 0.52	-0.07	0.726	✕ (NS)	Dental Caries (Post-RCT Recovery)
Healing_Days_Pre	14.00 ± 1.07	13.20 ± 1.21	+0.80	0.065	✕ (NS)	Delayed Wound Healing Post-Extraction

At baseline, clinical and subjective oral health parameters were assessed for both intervention groups to ensure comparability before the administration of *HETAFU Dia Smart gummies/Candies*. The Gingival Index (GI) was slightly higher in Group 2 (2.17 ± 0.33) compared to Group 1 (1.94 ± 0.28), although the difference approached but did not reach statistical significance ($p = 0.057$). Similarly, Plaque Index (PI) values were nearly identical between the groups (2.05 ± 0.29 in Group 1 vs. 2.10 ± 0.30 in Group 2; $p = 0.642$), indicating no significant disparity in oral hygiene status. Clinical Attachment Loss (CAL) was marginally greater in Group 1 (4.06 ± 0.54) than in Group 2 (3.77 ± 0.59), with a mean difference of +0.29 ($p = 0.171$), reflecting similar periodontal status across groups.

Subjective discomfort related to burning mouth syndrome, measured by VAS scores, also showed no significant differences (6.93 ± 0.88 in Group 1 vs. 7.13 ± 0.83 in Group 2; $p = 0.529$). For oral candidiasis, Group 1 exhibited slightly higher mean thrush area (27.73 ± 3.96 mm²) and thrush scores (3.20 ± 0.86) compared to Group 2 (25.33 ± 4.30 mm² and 2.80 ± 0.78 respectively), but these differences were not statistically significant (p-values > 0.1). Similarly, thrush-related VAS pain scores showed minimal differences ($p = 0.505$).

In terms of oral mucosal disorders, such as mucositis or lichen planus, Group 1 had a slightly higher score (1.67 ± 0.49) than Group 2 (1.53 ± 0.52), though not significant ($p = 0.473$). Lesion area values were nearly comparable (22.93 ± 4.38 mm² in Group 1 vs. 23.67 ± 3.62 mm² in Group 2; $p = 0.621$).

Objective evaluation of salivary gland function revealed similar unstimulated salivary flow rates between both groups (0.36 ± 0.07 ml/min in Group 1 vs. 0.35 ± 0.08 ml/min in Group 2; $p = 0.981$). Despite Group 1 reporting slightly higher subjective dryness scores (7.27 ± 0.70) than Group 2 (6.60 ± 0.83), this difference was not significant ($p = 0.25$). Taste dysfunction, assessed via VAS, showed nearly identical scores in both groups ($p = 0.841$). Dentine hypersensitivity, measured using the Schiff scale, also showed no significant variation between the groups ($p = 0.726$).

Finally, healing duration after minor oral surgery was slightly longer in Group 1 (14.00 ± 1.07 days) compared to Group 2 (13.20 ± 1.21 days), though the difference again did not achieve statistical significance ($p = 0.065$). Overall, none of the baseline variables showed statistically significant differences ($p > 0.05$), confirming that both groups were well matched prior to intervention and that any observed outcomes can be attributed to the effects of the HETAFU Dia Smart gummies/Candies intervention.

Table 4: Post-Intervention Comparison (Grouped by Cluster)

Cluster	Parameter	Control Group (Mean ± SD)	Intervention Group (Mean ± SD)	Mean Difference	p-value
1.Gingivitis / Periodontitis / Bone Loss	GI_Post	1.88 ± 0.56	1.07 ± 0.25	-0.812	≤0.001
	PI_Post	1.70 ± 0.44	1.06 ± 0.28	-0.642	≤0.001
	CAL_Post	1.25 ± 0.48	0.92 ± 0.40	-0.329	0.027
2. Burning Mouth Syndrome	VAS_Burning_Post	5.20 ± 1.61	1.33 ± 1.18	-3.867	≤0.001
3. Oral Infections (Thrush / Candidiasis)	Thrush_Area_Post (mm²)	9.93 ± 3.58	2.13 ± 1.24	-7.800	≤0.001
	Thrush_Score_Post	1.47 ± 0.64	0.53 ± 0.64	-0.933	0.008
	Thrush_VAS_Post	4.67 ± 2.10	2.00 ± 1.70	-2.667	≤0.001

4. Oral Mucosal Disorders	Mucositis_Post	1.27 ± 0.59	0.40 ± 0.50	-0.867	≤0.001
	Lesion_Area_Post (mm^2)	11.93 ± 3.29	2.53 ± 1.41	-9.400	≤0.001
5. Salivary Dysfunction / Xerostomia	Salivary_Flow_Post (ml/min)	0.33 ± 0.13	0.57 ± 0.14	+0.240	≤0.001
	Dryness_Score_Post	4.67 ± 1.45	1.93 ± 1.10	-2.733	≤0.001
6. Taste Dysfunction	Taste_VAS_Post	4.67 ± 1.98	1.60 ± 1.18	-3.067	≤0.001
7. Dental Caries (Post-RCT Recovery)	Schiff_Post	2.00 ± 1.07	0.93 ± 0.80	-1.067	≤0.001
8. Delayed Wound Healing	Healing_Days_Post	9.13 ± 2.50	5.07 ± 1.98	-4.067	≤0.001

The post-intervention comparison between the control and intervention groups across the eight oral conditions showed statistically significant improvements in the intervention groups who received HETAFU Dia Smart gummies/Candies alongside standard care. In Cluster 1, patients with gingivitis, periodontitis, or bone loss exhibited marked improvements in gingival index (GI), plaque index (PI), and clinical attachment level (CAL) scores. Specifically, the intervention group showed a significantly lower GI (1.07 ± 0.25 vs. 1.88 ± 0.56), PI (1.06 ± 0.28 vs. 1.70 ± 0.44), and CAL (0.92 ± 0.40 vs. 1.25 ± 0.48) with a p-value ≤ 0.001 for GI and PI, and 0.027 for CAL, indicating improved periodontal health.

In Cluster 2, participants with burning mouth syndrome reported substantial relief, with the mean VAS burning score dropping from 5.20 ± 1.61 in the control group to 1.33 ± 1.18 in the intervention group ($p \leq 0.001$). Cluster 3 dealing with oral infections such as candidiasis showed impressive reductions in lesion area ($9.93 \pm 3.58\ mm^2$ to $2.13 \pm 1.24\ mm^2$), lesion score (1.47 ± 0.64 to 0.53 ± 0.64), and subjective discomfort via VAS score (4.67 ± 2.10 to 2.00 ± 1.70), all statistically significant with $p \leq 0.001$.

Cluster 4 patients suffering from oral mucosal disorders demonstrated reductions in mucositis score (from 1.27 ± 0.59 to 0.40 ± 0.50) and lesion area (from $11.93 \pm 3.29\ mm^2$ to $2.53 \pm 1.41\ mm^2$), both highly significant ($p \leq 0.001$). In Cluster 5, related to xerostomia, there was a notable improvement in salivary flow rate (0.33 ± 0.13 to 0.57 ± 0.14 ml/min), and a reduction in subjective dryness (Dryness Score: 4.67 ± 1.45 to 1.93 ± 1.10), again highly significant ($p \leq 0.001$).

Cluster 6, representing taste dysfunction, showed enhanced taste perception with a drop in VAS scores from 4.67 ± 1.98 to 1.60 ± 1.18 ($p \leq 0.001$). In Cluster 7, patients recovering from dental caries treatment reported significantly reduced hypersensitivity, as indicated by the Schiff sensitivity scale (2.00 ± 1.07 to 0.93 ± 0.80, $p \leq 0.001$). Finally, in Cluster 8, patients with delayed post-extraction wound healing showed accelerated recovery, with the average healing time decreasing from 9.13 ± 2.50 to 5.07 ± 1.98 days ($p \leq 0.001$).

These findings suggest that HETAFU Dia Smart gummies/Candies, when used as an adjunct to standard dental therapy, significantly improve clinical and subjective outcomes across a range of diabetes-related oral health issues.

DISCUSSION

The findings of this study demonstrate that HETAFU Dia Smart gummies/Candies, when used as an adjunct to standard oral treatments, significantly improved clinical outcomes across various oral conditions. Notably, in the cluster of patients with gingivitis, periodontitis, and alveolar bone loss, reductions in Gingival Index (GI), Plaque Index (PI), and Clinical Attachment Loss (CAL) were observed post-intervention in the gummy group, suggesting anti-inflammatory and antimicrobial properties of the formulation. These improvements align with earlier studies on the role of functional foods in modulating oral biofilms and inflammation [11].

In burning mouth syndrome (BMS), a condition often linked to neuropathic mechanisms, the intervention group showed a marked decrease in the Visual Analog Scale (VAS) scores for burning sensation. This is likely due to the neuroprotective and mucosal-soothing properties of the gummies' bioactive components, such as essential fatty acids and polyphenols, which have previously shown efficacy in similar neuropathic conditions [12, 13].

Participants with oral candidiasis experienced significant reductions in lesion area, symptom severity, and discomfort scores. This supports findings by Chatterjee *et al*., [14], who reported that probiotic strains and essential oils disrupt fungal colonization and biofilm integrity. The synergistic use of gummies and topical antifungals may have enhanced antifungal efficacy through improved oral mucosal immunity [15].

In patients with oral mucosal disorders such as lichen planus, adjunct gummy therapy led to a drastic decrease in lesion area and mucositis scores. This could be attributed to the anti-inflammatory and mucosal healing agents present in the gummies, corroborating previous reports of phytotherapeutics aiding mucosal repair [16, 17].

Marked improvement in salivary flow rates and reduction in dryness scores among xerostomia patients confirms the salivary stimulatory effect of the formulation. Components like omega-3 and xylitol are known to activate salivary glands and maintain mucosal hydration [18, 19].

Similarly, taste dysfunction improved significantly, which might be related to micronutrient restoration and enhanced oral epithelial integrity, as shown in other interventional trials involving functional oral supplements [20].

Participants with post-endodontic discomfort (Dental Caries recovery group) and post-extraction delayed wound healing also demonstrated faster recovery and pain resolution. This further underscores the role of nutraceuticals in modulating tissue repair pathways, enhancing collagen synthesis, and controlling local inflammation [21, 22].

Overall, the integration of HETAFU Dia Smart gummies/Candies into standard care regimens appears to offer a novel, patient-friendly adjunctive option, particularly beneficial in polymorbid or non-compliant populations. However, long-term follow-up and larger randomized trials are needed to validate these findings and optimize dosage protocols across different oral disease clusters.

CONCLUSION

The present study demonstrated that HETAFU Dia Smart gummies/Candies, a novel formulation incorporating probiotics, essential oils, and micronutrients, significantly improved a wide spectrum of oral health parameters in diabetic individuals. Participants in the intervention group showed remarkable reductions in gingival inflammation, plaque accumulation, burning mouth sensations, oral candidiasis, mucosal lesions, xerostomia, taste disturbances, and delayed wound healing when compared to the control group. The consistent statistical significance across clusters supports the gummies' efficacy as an adjunct in managing diabetes-associated oral complications.

Given their palatable delivery format, ease of use, and multi-mechanistic action, HETAFU Dia Smart gummies/Candies may serve as a practical, non-invasive, and patient-friendly approach to enhance oral health and quality of life in diabetic populations. Future large-scale, multi-centered trials with longer follow-up periods are recommended to validate these findings and explore the long-term benefits and safety of such bioactive formulations in diverse diabetic cohorts.

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