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ACUTE EFFECTS OF A STANDARDIZED POLYHERBAL SUPPLEMENT ON HALITOSIS, DAYTIME SLEEPINESS, AND FATIGUE AMONG UNIVERSITY STUDENTS

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Abstract

This study investigated the acute effects of a standardized natural polyherbal formulation (Osuvita™) on halitosis, daytime sleepiness, alertness, and fatigue among undergraduate students at the Faculty of Agriculture, University of Peradeniya, Sri Lanka. Product quality and safety were evaluated through physicochemical, microbiological, heavy metal, and thin-layer chromatography fingerprinting analyses, while phytochemical properties were assessed using antioxidant activity (AA), total phenolic content (TPC), and total flavonoid content (TFC). A cross-sectional survey of 400 undergraduates assessed the prevalence of halitosis, daytime sleepiness, and fatigue and examined associated lifestyle factors. Subsequently, a 7-day intervention study evaluated symptom changes following consumption of the formulation using repeated-measures analysis. The formulation met safety standards, with microbial counts within acceptable limits and heavy metal levels below permissible thresholds. It showed high AA (87.64%), with TPC and TFC of 40 mg/g and 5.84 mg/g, respectively. The prevalence of self-reported halitosis and fatigue was 14%, while 20% reported daytime sleepiness. Halitosis was associated with tongue coating, stress, dry mouth, low water intake, and tooth-brushing frequency ($p < 0.05$). Daytime sleepiness was strongly linked to late-night academic and social activities ($p < 0.001$), while fatigue was associated with poor diet quality, short sleep duration, and emotional stress. After 7 days of consumption, significant reductions were observed in halitosis ($p < 0.001$) and daytime sleepiness ($p < 0.001$), with moderate improvement in fatigue ($p = 0.004$). Sensory acceptability was high with minor textural concerns, indicating the formulation's potential for short-term improvement in oral and functional health; long-term effects warrant further research.

Keywords: Herbal, Halitosis, Daytime sleepiness, Fatigue, Sleep quality

Abbreviations: ANCOVA, analysis of covariance; AOAC, Association of Official Analytical Chemists; CNS, central nervous system; DPPH, 2,2-diphenyl-1-picrylhydrazyl; ESS, Epworth Sleepiness Scale; FSS, Fatigue Severity Scale; ICP-MS, inductively coupled plasma mass spectrometry; Nrf2, nuclear factor erythroid 2-related factor 2; Rf, retardation factor; TLC, thin-layer chromatography; VSC, volatile sulfur compounds.

1. Introduction

University students frequently experience halitosis, fatigue, and reduced alertness conditions often underestimated that affect psychological well-being, academic performance, and social interactions [1-4]. The demanding university lifestyle—irregular sleep, academic stress, dietary inconsistencies—may predispose undergraduates to these interconnected challenges [5]. Safe, culturally appropriate, multifunctional interventions are therefore of growing interest.

Halitosis is persistent unpleasant breath odor originating from the oral cavity [2]. Approximately 85% of cases stem from intraoral causes: poor oral hygiene, tongue coating, gingivitis, and periodontitis [6]. Microbial degradation produces volatile sulfur compounds like hydrogen sulfide and methyl mercaptan [7]. Inflammatory conditions and xerostomia may intensify malodor by diminishing saliva's cleansing [8]. Halitosis also negatively affects self-esteem and relationships [2].

Fatigue—physical, cognitive, and emotional exhaustion—reduces purposeful activity [1]. It involves sleep deprivation, stress, poor nutrition, and sedentary behavior, with complex physiological interactions [9]. Prevalent among students facing academic demands, persistent fatigue impairs concentration, motivation, and achievement [10,11].

Alertness (cognitive readiness) is essential for learning [12]. Sleep restriction and mental exhaustion impair attention and executive function [4]. Reduced alertness often coexists with fatigue, forming a cycle affecting academic productivity and well-being [1].

Given the interconnection of oral health, fatigue, and cognition, interest in multi-target interventions is growing. Herbal formulations offer antimicrobial, anti-inflammatory, and antioxidant properties [13]. Approximately 80% of the global population relies on traditional medicines [14].

The polyherbal supplement (Osuvita™) commercially derives from Sri Lankan Ayurvedic practice, comprising *Glycyrrhiza glabra* (licorice), *Phyllanthus emblica* (Indian gooseberry), bark of *Mimusops elengi* (bulletwood tree), *Terminalia chebula* (Aralu), *Terminalia bellirica* (Bulu), *Syzygium aromaticum* (clove), *Elettaria cardamomum* (cardamom), *Zingiber officinale* (ginger), *Myristica fragrans* (nutmeg and mace), *Kaempferia galanga* (Inguru piyali), *Alpinia calcarata* (snap ginger), and bee honey. These contain antimicrobial, antioxidant, and anti-inflammatory constituents [15-19]. Clove, cardamom, licorice, and *Terminalia* species inhibit oral pathogens and VSC-producing bacteria, reducing malodor [18,20]. Ginger, nutmeg, and cardamom possess stimulant and adaptogenic properties that may enhance alertness and reduce fatigue [21-23]. Thus, the combined phytochemical profile may support both oral hygiene and cognitive vitality.

Despite widespread traditional use, empirical evidence on the acute functional effects of Osuvita™ among adults remains limited. Most studies have focused on individual extracts or clinical populations, leaving a gap in understanding its immediate benefits in healthy adults. Accordingly, this study aimed to evaluate the acute effects of a polyherbal supplement on halitosis, daytime sleepiness, and fatigue among undergraduates using a randomized pre–post crossover design. Using validated assessment tools, the study sought to generate evidence on its short-term efficacy to support safe, culturally appropriate health promotion strategies for university students.

2. Experimental

2.1. Polyherbal Supplement

The commercially available polyherbal supplement Osuvita™ (Wedagedara Producers (Pvt) Ltd, Alawwa, Sri Lanka) was used. The formulation comprises *Glycyrrhiza glabra* (licorice), *Phyllanthus emblica* (Indian gooseberry), *Mimusops elengi* (bulletwood tree bark), *Terminalia chebula* (aralu), *Terminalia bellirica* (bulu), *Syzygium aromaticum* (clove), *Elettaria cardamomum* (cardamom), *Zingiber officinale* (ginger), *Myristica fragrans* (nutmeg and mace), *Kaempferia galanga L.* (inguru piyali), *Alpinia calcarata* (snap ginger), and bee honey.

2.2. Phytochemical and Safety Profiling of a Polyherbal Formulation

Moisture content was determined via oven-drying (AOAC 925.10). Microbial safety was assessed through total plate count, coliforms, *Escherichia coli*, yeast and mold, and *Staphylococcus aureus* enumeration following ISO/AOAC guidelines. Heavy metals (lead, cadmium, mercury, arsenic) were quantified using ICP-MS (Agilent 7900, USA) after microwave digestion. Phytochemical profiling was performed via TLC fingerprinting against raw material standards. Antioxidant activity was evaluated via 2,2-diphenyl-1-picrylhydrazyl (DPPH) assay, alongside total phenolic content using Folin–Ciocalteu method and flavonoid content determination using spectrophotometric methods [24,25].

2.3. Methods for Evaluating Polyherbal Supplement Effects in Humans

This single-group, pre-post intervention study evaluated the acute effects of the polyherbal supplement on halitosis, daytime sleepiness, and fatigue. Conducted at the Faculty of Agriculture, University of Peradeniya, Sri Lanka, the study received ethical approval from the Faculty Ethics Committee (Approval No. ECC/2025/E/073) and was conducted in accordance with the 1975 Declaration of Helsinki.

All participants provided informed consent. Participation was voluntary, and withdrawal was permitted at any time. Data was reported at group level without personal identifiers; no personal data were collected. All data were handled with strict confidentiality and transmitted via secure connection, with access restricted to the research team.

Eligible participants were undergraduate students in Faculty of Agriculture, University of Peradeniya, aged 19-28 years, with valid university ID. Exclusion criteria were foreign nationality, Phase 1 (cross-sectional) assessed condition prevalence. A sample of 400 (Lemeshow formula) completed a secure online questionnaire (100% response rate). Phase 2 (clinical trial) enrolled students from Phase 1 with halitosis (n=54) or severe fatigue/sleepiness (n=80), randomly assigned to experimental or control groups. Experimental groups received 1g supplement thrice daily for seven days; controls received no intervention. A subset (n=15) from the halitosis group had volatile sulfur compounds measured via Halimeter.

2.4. Study Instruments

Halitosis: Subjective assessment used the 15-item Self-perceived Halitosis Questionnaire (Halfins), with scores ≥14 indicating halitosis [26]. Severity was categorized as none (0-13), mild (14-22), moderate (23-31), or severe (32-45). The questionnaire was validated through an expert panel comprising medical practitioners and a dental surgeon to ensure content relevance and clarity.

Objective assessment was performed using a portable Halimeter which detects volatile sulfur compounds in exhaled breath [27].

Daytime Sleepiness: Measured with the ESS. Scores ≥11 indicated excessive daytime sleepiness [4]. Severity was categorized as none (0-10), mild (11-12), moderate (13-15), or severe (16-24).

Fatigue: The FSS measures fatigue interference with daily functioning over the past week. The final score is the mean of its 9 items (range 1-7), with higher scores indicating greater severity [1]. Severity was categorized as none (1.0–3.0), mild (3.1–4.0), moderate (4.1–5.0), or severe (5.1–7.0).

All questionnaires were available in English, Sinhala, and Tamil, and were pre-tested in a pilot study (n=25).

2.5. Statistical Analysis

Data were analyzed using SPSS version 25. Descriptive statistics summarized baseline characteristics and prevalence outcomes. Associations between categorical variables and outcomes were examined using Chi-square (χ^2) tests (significance at $p<0.05$). For the intervention, ANCOVA was used to compare post-test scores between groups, adjusting for baseline values. Effect sizes were calculated using partial eta squared (η^2). All tests were two-tailed.

3. Results

3.1. Polyherbal Supplement Product Quality and Safety

The physicochemical analysis confirmed the product was safe and effective in composition. Moisture content was around 19.1% w/w, and no synthetic dyes or heavy metals such as cadmium, mercury, or arsenic were detected (Table 1). The antioxidant activity was high at 87.64%, total flavonoid content was 5.84 mg/g and total phenolic content was 40 mg/g, indicating good potential for reducing oxidative stress and fatigue. Microbial levels were within permissible limits, showing that the product is safe for consumption.

Table 1. Product Quality and Safety Parameters of Osuvita™

Parameter	Result
Moisture Content	19.1%
Aerobic Plate Count	1.7×10^4 CFU/g
Yeast and Moulds	7.3×10^2 CFU/g
Coliforms, *Escherichia coli*, *Staphylococcus aureus*	Not detected / <10 CFU/g
Lead (Pb)	0.70 mg/kg
Cadmium, Mercury, Arsenic	Not detected
Antioxidant Activity	87.64%
Total Phenolic Content	40 mg/g
Total Flavonoid Content	5.84 mg/g

As given in Table 2, TLC fingerprint confirmed multiple phytochemical constituents consistent with raw ingredients. Several bands showed exact matches in Rf and color (0.04, 0.07, 0.47, 0.53, 0.67). Some variations in color intensity and Rf values were observed (0.13, 0.20, 0.29, 0.73). Overall fingerprint demonstrated significant similarity to the standard mixture.

Table 2. TLC Fingerprint Profile of Osuvita™ Compared with Standards

Rf (Standard)	Color (Standard)	Rf (Sample)	Color (Sample)	Match/Variation
0.04	Brown	0.04	Brown	Match
0.07	Brown	0.07	Brown	Match
0.13	Dark purple	0.09	Orange	Variation
0.20	Orange	0.13	Purple	Variation
0.29	Yellow	0.20	Orange	Variation
0.33	Dark purple	0.29	Yellow	Variation
0.40	Purple	0.33	Dark purple	Match
0.45	Pink	0.40	Orange	Variation

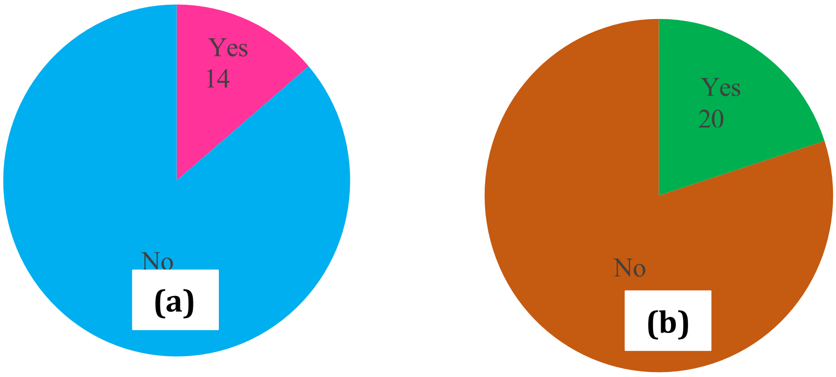
0.48	Purple	0.47	Purple	Match
0.51	Purple	0.53	Purple	Match
0.53	Purple	0.60	Purple	Match
0.67	Purple	0.67	Purple	Match
0.73	Orange	0.80	Purple	Variation
0.80	Purple	0.93	Orange	Variation

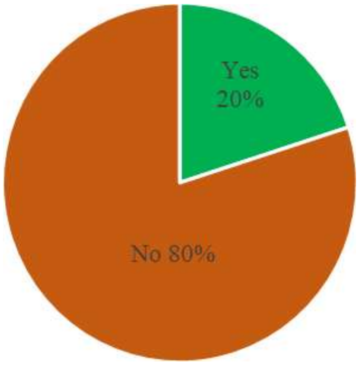
3.2. Prevalence of Halitosis, Fatigue, and Daytime Sleepiness

In this study 400 undergraduate students, 14% reported halitosis, 20% reported fatigue, and 20% demonstrated daytime sleepiness (Figure 1). Statistically significant associations ($p<0.05$) with halitosis included tongue coating, stress level, dry mouth, inadequate water intake, and tooth brushing frequency. No significant associations were found for bleeding gums, skipping meals, frequent sore throat, jaw pain, or thick saliva ($p>0.05$) (Table 3).

Daytime sleepiness showed significant associations with staying up late for academic work ($p<0.001$), using electronic devices late at night ($p=0.031$), and social activities at night ($p<0.001$). Long-distance travel showed borderline significance ($p=0.050$). No significant association was observed between daytime sleepiness and poor sleep environment or skipping meals ($p>0.05$) (Table 4).

Fatigue showed significant associations with poor diet or skipping meals ($p=0.030$), sleeping <6 hours ($p=0.018$), and emotional stress ($p<0.001$). No significant association was found between fatigue and excessive energy drink consumption, medication side effects, or part-time employment ($p>0.05$) (Table 5).





(c)

Figure 1: Self-perceived prevalence of (a) halitosis, (b) daytime sleepiness, and (c) fatigue

Table 3. Association Between Oral, Lifestyle, and Stress-Related Factors and Halitosis

Variable	Category	Halitosis-n (%)	No Halitosis-n (%)	χ^2	DF	p-value
Tongue Coating	Present (80)	20 (25.0)	60 (75.0)	10.67	**1**	**0.001***
	Absent (320)	35 (10.9)	285 (89.1)			
Bleeding Gums	Yes (58)	10 (17.2)	48 (82.8)	0.70	1	0.404
	No (342)	45 (13.2)	297 (86.8)			
Skipping Meals	Yes (123)	2 (1.6)	121 (98.4)	1.24	1	0.266
	No (377)	53 (14.1)	324 (85.9)			
Stress Level	Low (29)	2 (6.9)	27 (93.1)	10.14	**2**	**0.006***
	Moderate (335)	42 (12.5)	293 (87.5)			
	High (36)	11 (30.6)	25 (69.4)			
Frequent Sore Throat	Yes (65)	12 (18.5)	53 (81.5)	1.45	1	0.228
	No (335)	43 (12.8)	292 (87.2)			
Dry Mouth	Yes (123)	22 (17.9)	101 (82.1)	7.90	**1**	**0.005***
	No (277)	33 (11.9)	244 (88.1)			
Adequate Water Intake	Yes (193)	19 (9.8)	174 (90.2)	4.80	**1**	**0.029***
	No (207)	36 (17.4)	171 (82.6)			
Jaw Pain	Yes (31)	6 (19.4)	25 (80.6)	0.89	1	0.345
	No (369)	49 (13.3)	320 (86.7)			
Thick Saliva	Yes (19)	3 (15.8)	16 (84.2)	0.09	1	0.767

	No (381)	52 (13.6)	329 (86.4)			
Tooth Brushing Frequency	Once daily (79)	17 (21.5)	62 (78.5)	5.01	**1**	**0.025***
	Twice daily (321)	38 (11.8)	283 (88.2)			

*Statistically significant association (p<0.05), DF: degrees of freedom

Table 4: Association Between Selected Factors and Daytime Sleepiness

Variable	Daytime Sleepiness-n (%)	No Daytime Sleepiness-n (%)	χ^2 (df=1)	DF	P-value
Staying up late for academic work	74 (31.4%)	162 (68.6%)	46.39	1	<0.001*
Not staying up late	6 (3.7%)	158 (96.3%)			
Using electronic devices late at night	52 (24.0%)	165 (76.0%)	4.66	1	0.031*
Not using electronic devices late	28 (15.3%)	155 (84.7%)			
Long distance travel to university	18 (38.3%)	29 (61.7%)	3.86	1	0.050*
Not long-distance travel	62 (24.5%)	191 (75.5%)			
Poor sleep environment	25 (22.7%)	85 (77.3%)	0.71	1	0.401
Not poor sleep environment	55 (19.0%)	235 (81.0%)			
Social activities at night	74 (49.7%)	75 (50.3%)	120.73	1	<0.001*
Not social activities at night	6 (2.6%)	225 (97.4%)			
Skipping meals / poor diet	17 (23.3%)	56 (76.7%)	0.56	1	0.453
Not skipping meals	63 (27.8%)	164 (72.2%)			

*Statistically significant association (p<0.05), DF: degrees of freedom

Table 5: Association Between Selected Factors and Fatigue

Variable	Fatigue-n (%)	No Fatigue-n (%)	χ^2	DF	P-value
Poor diet / Skipping meals	43 (25.0%)	129 (75.0%)	4.76	1	0.030*
Not poor diet	37 (16.2%)	191 (83.8%)			
Excessive energy drinks	3 (15.0%)	17 (85.0%)	0.34	1	0.563
Not excessive energy drinks	77 (20.3%)	302 (79.7%)			
Sleeping less than 6 hours	55 (24.1%)	173 (75.9%)	5.63	1	0.018*
≥6 hours sleep	25 (14.5%)	147 (85.5%)			
Medication side effects	15 (25.0%)	45 (75.0%)	1.10	1	0.294
No medication side effects	65 (19.1%)	275 (80.9%)			
Part-time employment	6 (20.7%)	23 (79.3%)	0.01	1	0.923
No part-time employment	74 (20.0%)	297 (80.0%)			
Emotional stress	57 (27.9%)	147 (72.1%)	16.41	1	<0.001*
No emotional stress	23 (11.7%)	173 (88.3%)			

* Statistically significant association (p<0.05), DF: degrees of freedom

3.3. Effectiveness of the Intervention on Halitosis, Daytime Sleepiness, and Fatigue

Baseline halitosis scores were comparable between control (16.14±4.19) and treatment (16.48±4.16) groups. Post-intervention, the treatment group showed substantial reduction (10.15±4.16) versus a slight decrease in controls

(14.96±3.93). After adjusting for baseline using ANCOVA, the difference was significant between groups, $F(1,51)=138.79$, $p<0.001$, with large effect size ($\eta^2=0.731$) (Table 6).

Marked categorical halitosis improvement was observed (Figure 2a). At baseline, none were halitosis-free; post-supplementation, substantial shifting to "no halitosis" occurred, indicating clinically meaningful improvement. Halimeter readings confirmed these findings, with improved breath quality and complete resolution of mild halitosis cases (Figure 2b).

Halimeter measurements corroborated the clinical findings (Figure 2b). Post-intervention, participants with good oral freshness increased, and mild halitosis cases were completely resolved, indicating effective reduction of volatile sulfur compounds.

Baseline Epworth Sleepiness Scale (ESS) scores were comparable (control: 15.71±2.24; treatment: 15.71±2.12). Post-intervention, treatment group showed significant reduction (12.30±2.12) while controls remained unchanged (15.48±2.24). Group×time interaction was significant, $F(1,77)=199.21$, $p<0.001$, with large effect size ($\eta^2=0.721$) (Table 6). Categorical analysis revealed shift from moderate and severe sleepiness toward mild and low categories (Figure 3a).

Baseline Fatigue Severity Scale (FSS) scores were comparable (control: 5.21±0.68; treatment: 5.21±0.60). Post-intervention, treatment group showed reduction (4.75±0.60) versus control (5.23±0.68). Group×time interaction was significant, $F(1,77)=9.03$, $p=0.004$, with small-moderate effect size ($\eta^2=0.105$) (Table 6). Categorical analysis showed shift from severe to mild fatigue (Figure 3b).

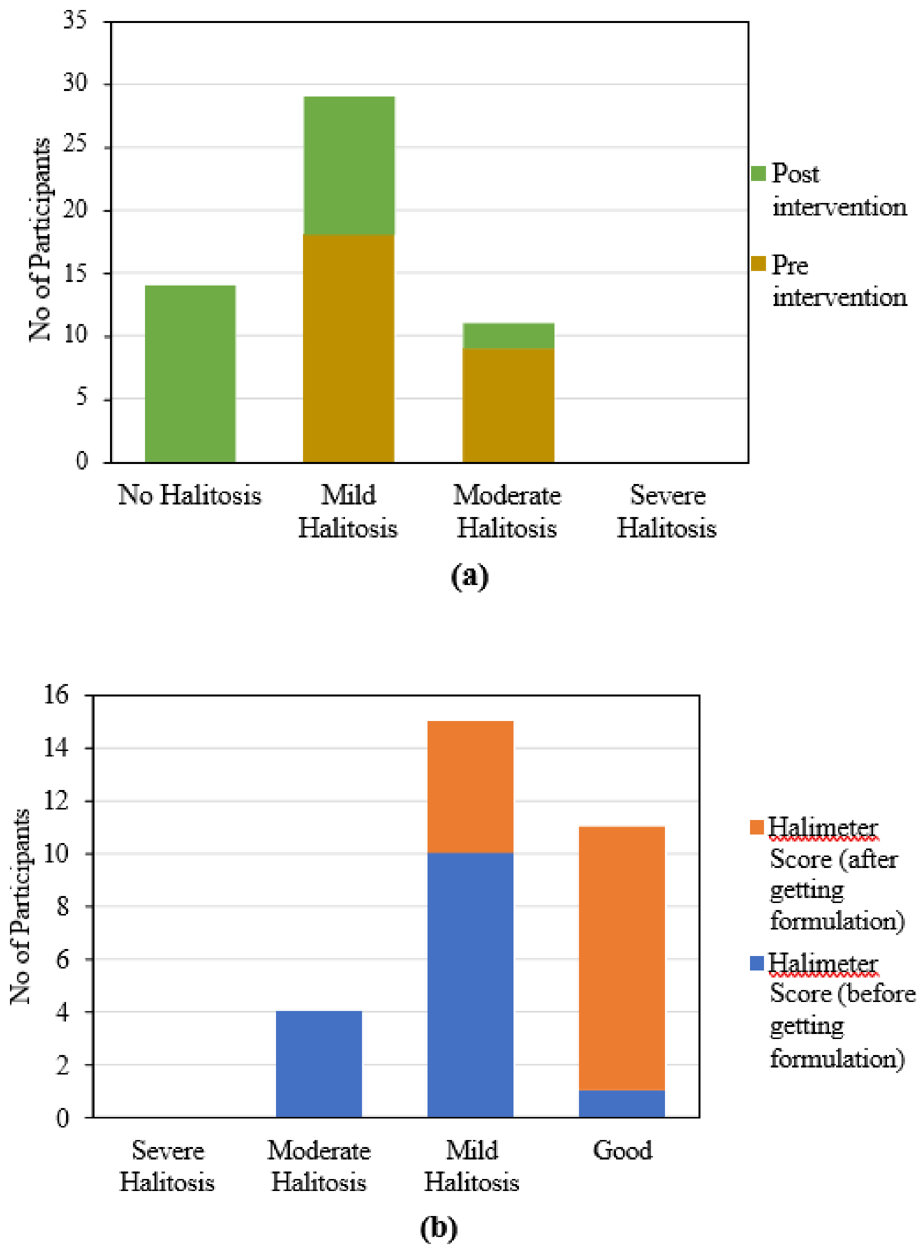
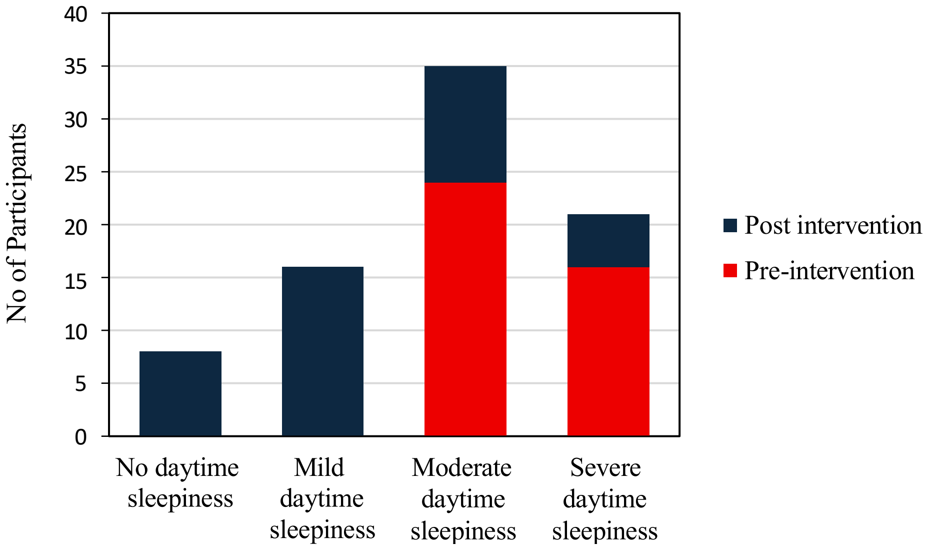


Figure 2: (a) Self-perceived halitosis scores pre/post-intervention in control and treatment groups (n=27 each); (b) Oral odor freshness (Halimeter) pre/post-intervention in control and treatment groups (n=15 each).



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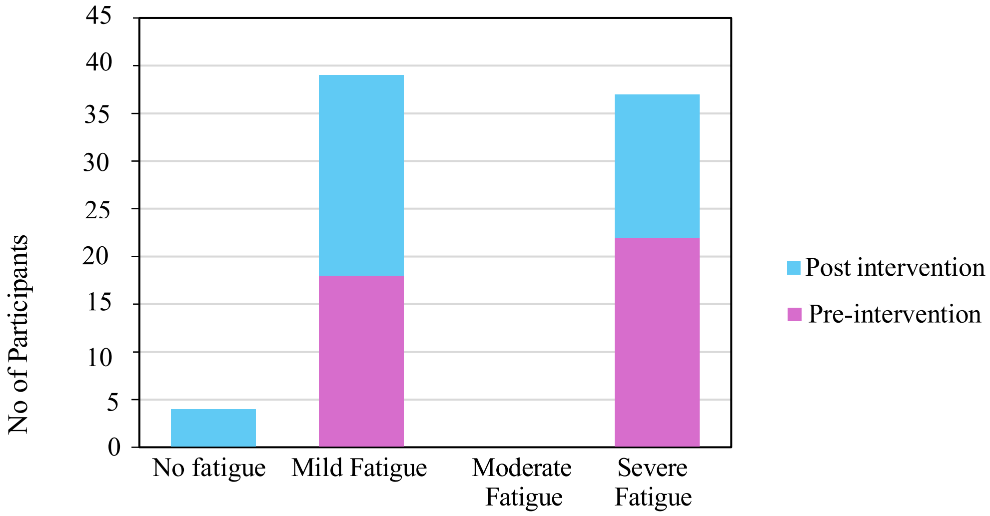

(b)

Figure 3: (a) Pre/post-intervention daytime sleepiness scores in control and treatment groups (n=40 each); (b) Pre/post-intervention fatigue scores in control and treatment groups (n=40 each)

Table 6. Effects of the Intervention on Halitosis, Daytime Sleepiness (ESS), and Fatigue (FSS)

Outcome	Group	Pretest Mean±SD	Post-test Mean±SD	F (DF)	p-value	Partial η²
Halitosis Score	Control (n=27)	16.14±4.19	14.96±3.93	138.79	<0.001	0.731
	Treatment (n=27)	16.48±4.16	10.15±4.16	(1,51)		
Daytime Sleepiness (ESS) Score	Control (n=40)	15.71±2.24	15.48±2.24	199.21	<0.001	0.721
	Treatment (n=40)	15.71±2.12	12.30±2.12	(1,77)		
Fatigue (FSS) Score	Control (n=40)	5.21±0.68	5.23±0.68	9.03	0.004	0.105
	Treatment (n=40)	5.21±0.60	4.75±0.60	(1,77)		

Values are presented as mean±standard deviation.

Group differences at posttest were analyzed using ANCOVA, adjusting for baseline (pretest) scores.

Partial eta squared (η^2) indicates effect size (small≥0.01, medium≥0.06, large≥0.14).

ESS=Epworth Sleepiness Scale;

FSS=Fatigue Severity Scale

p-value<0.05 is considered statistically significant.

F (df) refers to the F-statistics from the ANCOVA test, which compares the groups' post-test scores while adjusting for baseline values. The number in parentheses shows the degrees of freedom (DF) for the analysis: the first number (numerator df) represents the effect (group×time), and the second number (denominator df) represents the residual or error.

3.4. Qualitative Evaluation of Sensory Attributes and User Experience

Participants reported positive perceptions of the formulation (Figure 4). The product had pleasant herbal aroma and agreeable taste. Absence of bitterness was appreciated. Fragrance from clove, cardamom, ginger, and nutmeg enhanced experience. Extended chewing was positively perceived, creating sustained freshening effect. No addiction or adverse reactions reported. Discomfort limited to minor textural concerns. Natural composition enhanced user confidence. Several participants reported enhanced alertness and reduced fatigue. Limitations included coarse, gritty texture. Prolonged chewing was occasionally inconvenient during busy schedules.

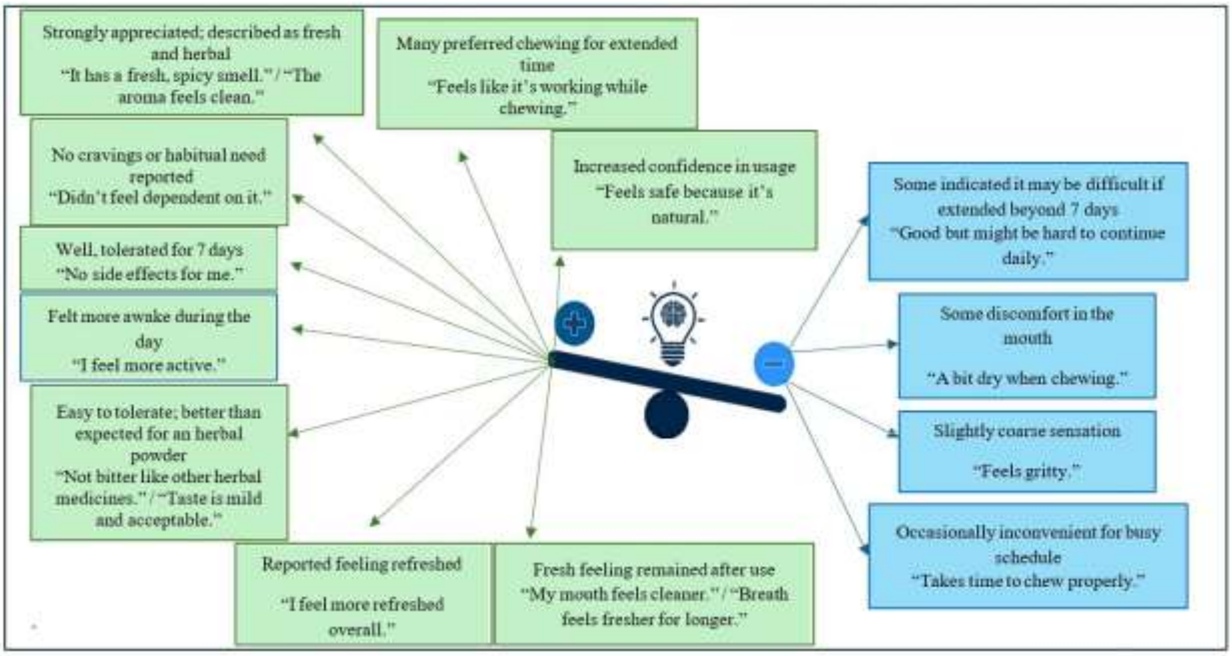

Figure 4: Qualitative Evaluation of Sensory Attributes, User Experience, and Acceptability of the Herbal Formulation

4. Discussion

4.1. Quality and Safety Analysis

Physicochemical and microbiological analyses confirmed that Osuvita™ met safety requirements for dried herbal products. Moisture content was 19.1% (w/w), within accepted limits. Microbial counts were <10^5 CFU/g, indicating good hygienic manufacturing practices [28]. Absence of coliforms, *Escherichia coli*, and *Staphylococcus aureus* confirmed satisfactory sanitary handling. Lead was detected at 0.70 mg/kg, while cadmium, mercury, and arsenic were below detectable limits, all within international guidelines [29]. High antioxidant activity (87.64%), with total phenolic content of 40 mg/g and total flavonoid content of 5.84 mg/g, indicated strong free radical scavenging capacity [13]. TLC fingerprint similarity to the standard mixture validated product authenticity and quality.

4.2. Prevalence of Halitosis, Fatigue, and Daytime Sleepiness

Halitosis prevalence (14%) was lower than reported among Bangladeshi students (55.97%) [3], possibly reflecting population differences. Significant associations with poor oral hygiene and stress were identified, consistent with prior research [2,3,30]. Fatigue and daytime sleepiness prevalence aligned with studies demonstrating links to poor sleep quality, examination stress, and irregular schedules [10,31]. Electronic device use before bedtime and poor diet exacerbate these conditions [4,32]. In Sri Lankan undergraduates, academic stress (72%), mental fatigue (54%), and sleeplessness (33%) have been reported as key triggers [33], supporting the interconnected role of lifestyle factors.

4.3. Effectiveness of the Intervention on Halitosis, Daytime Sleepiness, and Fatigue

The significant reduction in halitosis scores, with 73.1% variance explained by the intervention, demonstrates robust efficacy. Halimeter validation confirmed reduced volatile sulfur compounds, supporting the formulation's capacity to address oral malodor through direct antimicrobial activity of bioactive compounds such as eugenol from clove. The categorical shift toward "no halitosis" indicates clinically meaningful improvement.

The significant reduction in daytime sleepiness, with 72.1% variance explained, demonstrates robust efficacy. Control group stability confirms improvements were intervention-attributable.

Bioactive compounds in ginger and cardamom may possess mild stimulatory properties that enhance alertness. Additionally, reduced halitosis may alleviate social anxiety that exacerbates sleepiness. These findings align with research demonstrating that targeted interventions can reduce excessive daytime sleepiness [34].

The moderate reduction in fatigue (10.5% variance explained) is consistent with research showing short-term interventions can moderately alleviate fatigue [35]. The modest effect compared to sleepiness may reflect the multifactorial nature of fatigue requiring longer intervention periods.

4.4. Qualitative Evaluation

Positive sensory perceptions, particularly absence of bitterness, enhanced short-term adherence. Extended chewing may facilitate bioactive compound interaction with oral tissues. Absence of adverse reactions confirms short-term safety. Reported alertness and fatigue reduction may relate to stimulatory and adaptogenic properties of ginger and cardamom. Textural concerns represent the primary area for formulation optimization.

4.5. Possible Mechanisms of Action of Osuvita™ in the Management of Halitosis, Daytime Sleepiness, Alertness Enhancement, and Fatigue Reduction

The standardized polyherbal formulation Osuvita™, characterized by high antioxidant potential, phenolic content, and consistent TLC fingerprinting, derives synergistic effects from its Ayurvedic ingredients, contributing to significant reductions in halitosis (partial η^2=0.731), daytime sleepiness (η^2=0.721), and fatigue (η^2=0.105) over seven days. Figure 5 depicts these mechanisms driven by antimicrobial, anti-inflammatory, antioxidant, neuroprotective, adaptogenic, and mild CNS-modulating activities.

Halitosis arises from volatile sulfur compounds (VSCs) produced by anaerobic oral bacteria. Osuvita™ targets this through antimicrobial and deodorizing actions: clove (eugenol) inhibits VSC-producing bacteria (*P. gingivalis*, *S. sanguinis*) and biofilm formation [7,17]; licorice (glycyrrhizin, liquiritigenin) inhibits oral pathogens and reduces gingival inflammation and VSC production [16,36]; ginger ([6]-gingerol) provides antimicrobial and anti-inflammatory support [21]; cardamom (1,8-cineole), *Terminalia chebula* (gallic acid), and *Terminalia bellirica* (ellagic acid) contribute antimicrobial and antioxidant properties [18,37,38]; Indian gooseberry (ellagic acid) stimulates saliva to dilute VSCs [39]; and bee honey adds antibacterial activity [40]. These synergistic actions explain halimeter-validated reductions.

Daytime sleepiness involves oxidative stress and neurotransmitter imbalances. Osuvita™ promotes alertness via CNS modulation: clove and ginger provide sensory activation and mild CNS stimulation [41,42]; cardamom enhances dopamine and serotonin activity [20]; Indian gooseberry activates Nrf2, protecting against cognitive impairment [39]; nutmeg (myristicin) provides CNS modulation [43]; snap ginger exerts neuroprotective actions [15]; and bee honey supplies glucose for rapid energy [44]. These mechanisms align with significant ESS improvements.

Fatigue involves oxidative stress, inflammation, and energy disruptions. Osuvita™'s adaptogenic profile alleviates fatigue: licorice modulates cortisol and reduces oxidative fatigue [16]; Indian gooseberry enhances mitochondrial function via Nrf2 [39,45]; ginger boosts thermogenesis and anti-fatigue activity [14]; clove and cardamom improve circulation; bulletwood bark lowers inflammatory markers [19]; and bee honey provides rapid glucose energy [44]. These explain FSS reductions, though the modest effect size suggests longer exposure may benefit multifactorial fatigue.

Figure 5: Possible Mechanisms of Action in the Management of Halitosis, Daytime Sleepiness, Alertness Enhancement, and Fatigue Reduction

4.6. Limitations of the Study

Few limitations should be acknowledged. The seven-day intervention precludes determination of long-term sustainability. The relatively small sample comprised students with similar age and backgrounds, limiting generalizability. Outcomes were primarily assessed using self-reported scales, which may be influenced by bias. External factors including diet, sleep, stress, and caffeine intake were not strictly controlled. Biochemical markers were not measured. Future studies should include larger, diverse populations, longer interventions, and objective biomarkers.

5. Conclusions

The formulation was microbiologically safe, exhibited strong antioxidant capacity, and contained phytochemical profiles consistent with its declared ingredients. In undergraduates, a short-term intervention significantly reduced self-perceived halitosis severity and objective volatile sulfur compound levels, shifting participants toward normal breath freshness. It also decreased daytime sleepiness and moderately alleviated fatigue, with participants reporting enhanced energy and well-being. Qualitative feedback confirmed good sensory acceptability and pleasant taste. These findings support this polyherbal formulation as a safe, culturally relevant intervention for addressing oral malodor and fatigue in young adults.

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7. Conflict of interest

The authors received no specific funding for this work and no conflicts of interest.

8. Author contributions

Conceptualization, W.G.R.L. Kumarasiri and G.M. Somaratne; methodology, W.G.R.L. Kumarasiri, G.M. Somaratne and A.Chandrasekara; validation, W.G.R.L. Kumarasiri, G.M.

Somaratne and A. Chandrasekara; formal analysis, W.G.R.L. Kumarasiri, G.M. Somaratne and H.M.N.S. Bandara; investigation, G.M. Somaratne, A. Chandrasekara and E.M.N. M. Ekanayake; resources, W.G.R.L. Kumarasiri, G.M. Somaratne and M.A.J.N. Wijayarathna; data curation, W.G.R.L. Kumarasiri, G.M. Somaratne, A.Chandrasekara and M.A.J. N. Wijayarathna; writing - original draft preparation, W.G.R.L. Kumarasiri, G.M. Somaratne, G.J.Jayawardhana and A. Chandrasekara, writing- review and editing, W.G.R.L. Kumarasiri, G. M. Somaratne, G.J. Jayawardhana, U. Walallawita and A. Chandrasekara, visualization, W.G.R.L. Kumarasiri, G.M. Somaratne, G.J. Jayawardhana, and A. Chandrasekara, supervision, G.M. Somaratne and A.Chandrasekara All authors have read and agreed to the published version of the manuscript.

9. Ethical considerations

This study received ethical approval from the Ethical Review Committee, Faculty of Agriculture, University of Peradeniya. (authorsal No. ECC/2025/E/073). The study protocol was conformed to the ethical guidelines of the Declaration of Helsinki.

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