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Efficacy of Dichrostachys Glomerata Supplementation on Overweight and Mildly Obese Adult's Weight, Mood, and Health-Related Quality of Life: A Randomized Double-Blind Placebo-Controlled Trial

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ABSTRACT

Despite their widespread use, research is needed to evaluate the weight loss and related health/wellness outcomes of herbal plants. Preliminary research found that the fruit of *Dichrostachys glomerata* is safe and has potential weight loss effects. This study aimed to examine the effect of a standardized powder of *D. glomerata* fruit pods (DYG-400®) on weight, food cravings, mood, and health-related quality of life of overweight and mildly obese adults. In this CONSORT-compliant double-blind placebo-controlled trial, 56 adults (Mean [*M*] age = 44.50, *M* [body mass index] BMI = 31.66) were randomized to either the *D. glomerata* Group (DG; 300 mg/d) or Placebo Group (PG; rice protein, 300 mg/d) for 60 days. Participants weight was assessed along with self-report assessments of the Food Cravings Questionnaire, CDC Health-related Quality of Life, Perceived Stress Scale, Trait Anxiety Inventory, and Profile of Mood States at Baseline, Day 30, and Day 60. The data were collected from March 2023 to June 2023 and stored electronically, and analyzed using general linear models with repeated measures. DG lost more weight at Day 60 compared to PG, $p = .05$ (4.11 *vs.* 2.19 lbs). DG had reduced food cravings from Baseline to Day 30 and Day 60 compared to PG, $p < .001$. Perceived stress, $p < .001$, and mood, $p = .017$, improved from Baseline to Day 60 for DG compared to PG. Anxiety decreased from Baseline to Day 60 for DG and from Baseline to Day 30 for PG, $p < .001$. Health-related Quality of Life improved for DG compared to PG, $p < .001$. *D. glomerata* (DYG-400®) may be an effective herbal intervention to promote weight loss and health. Extended clinical trials across diverse populations and settings are needed.

Clinical trial registry number and website: ISRCTN10099861, https://doi.org/10.1186/ISRCTN10099861.

KEYWORDS

Dichrostachys glomerata; dietary supplement; integrative medicine; medicinal herbs; mood; weight loss

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Introduction

Overweight and obesity are chronic complex conditions defined by excessive fat deposits that can impair health. Globally, about 43% of adults are overweight, with 16% classified as obese (WHO 2024). Individuals with overweight or obesity face an increased risk of numerous diseases and early mortality (CDCP 2021). Beyond these health risks, overweight and obesity are linked to negative mental health outcomes, including reduced health-related quality of life, mood disturbances, food cravings, stress, and anxiety (Kolotkin and Andersen 2017). Consequently, weight loss and weight management are public health priorities (Riaz et al. 2018).

Common interventions for reducing excess weight include counseling, lifestyle management, pharmacological, and surgical methods. While these interventions can be effective, they are often expensive, time-consuming, and associated with side effects (Kim 2020). Additionally, pharmacological and surgical interventions are typically reserved for moderately to severely obese individuals due to their higher success rates in these populations (Arterburn et al. 2020).

Overweight and mildly obese adults are ideal candidates for weight loss interventions using supplements because they tend to respond better and have fewer metabolic complications. Modest weight loss in this group can significantly improve health markers, including reducing cardiovascular risk and enhancing insulin sensitivity (Wadden et al. 2011; Jensen et al. 2014).

However, despite the widespread use of dietary supplements, there is a lack of randomized controlled trials evaluating their effectiveness for weight loss and related health outcomes (Bray et al. 2018; Watanabe et al. 2020). One such plant, *Dichrostachys glomerata*, has garnered attention for its potential weight loss effects. The fruits and seeds of *D. glomerata* are edible and commonly used as a spice in western Cameroon (Tchiégang and Mbougueng 2005).

Dichrostachys glomerata contains various bioactive components, including flavonoids, phenolic compounds, alkaloids, tannins, saponins, and terpenoids (Djuissi et al. 2021). The standardized powder of *D. glomerata* fruit pods (DYG-400®) is prepared by extracting the fruit pods with aqueous ethanol, followed by concentration and drying. *In vitro* and *in vivo* research has demonstrated that *D. glomerata* has antioxidant properties and the ability to lower fasting serum glucose levels and glycated hemoglobin (Etoundi et al. 2010; Kuate et al. 2010, 2011). Additionally, *D. glomerata* exhibits anti-inflammatory and fat regulation activities in animals and humans with obesity and type 2 diabetes (Dieudonne et al. 2013; Kuate et al. 2013; Azantsa et al. 2015; Kim et al. 2022). Preliminary research indicates that *D. glomerata* supplementation improves body composition and some health markers in otherwise healthy adults (Sowinski et al. 2021). Furthermore, *D. glomerata* has been found safe in rats and genotoxicity tests (Kothari et al. 2014).

Further clinical trials are needed to determine the efficacy of *D. glomerata* fruit pods (DYG-400®) on weight and related health outcomes. Therefore, the purpose of this study was to investigate the effects of DYG-400® on weight, food cravings, mood, and health-related quality of life in overweight and mildly obese adults using a randomized, double-blind, placebo-controlled trial design. The primary outcome was weight loss, with secondary outcomes including food cravings, mood, anxiety, stress, and health-related quality of life.

Methods

Study design

The trial was conducted and reported in accordance with the Consolidated Standards of Reporting Trials (CONSORT) guidelines to ensure transparency and completeness in reporting randomized controlled trials (Schulz et al. 2010). This study was approval by Sterling Institutional Review Board (10504-HAHausenblas) in compliance with the Declaration of Helsinki standards for ethical principles regarding human participant research and registered with a clinical trial registry (ISRCTN10099861, https://doi.org/10.1186/ISRCTN10099861). This study was conducted in a double-blind, parallel treatment, randomized, placebo-controlled manner. Participants were randomized to the intervention and control groups in a 1:1 ratio. Participants were automatically assigned to their respective groups by a computer program upon enrollment. This ensured complete allocation concealment by preventing researchers and participants from knowing which group they would be assigned to before enrollment, thereby minimizing selection bias. A blinded research assistant generated the random allocation sequence, enrolled participants, and assigned participants to the intervention. The independent variable was the *D. glomerata* dietary supplementation. The dependent variables were body weight (primary outcome) and food cravings, mood, anxiety, stress, and health-related quality of life (secondary outcomes). A medium effect size was assumed, based on previous research evaluating the effects of dietary supplements on weight loss (Etoundi et al. 2010; Sowinski et al. 2021). Sample size power calculation indicated that 25 participants were needed in each group to achieve a power of 80% and alpha $< .05$.

Participants

Participants were 56 overweight and mildly obese adults (Mean [*M*] age = 44.50, age range = 25–60 years, $n = 43$ women; *M* body mass index [BMI] = 31.66).

Inclusion criteria

Overweight and mildly obese adults (BMI between 25.00 and 34.99) were selected as they represent the largest proportion of the overweight/obese population and are most likely to benefit from a dietary supplementation weight loss intervention.

Exclusion criteria

Individuals meeting any of the following criteria were excluded from participation: (1) any metabolic or endocrine related dysregulation including but not limited to: diagnosis of type I or type II diabetes, liver, kidney, or pancreatic dysfunction; (2) history of sleep-affecting disorders; (3) recent highly stressful events within 4 weeks of baseline; (4) usage of weight-influencing medications within 1 month of baseline; (5) use of Ca channel blockers, anxiolytics or SSRIs, no more than 5 times per month, and not within seven days of baseline; (6) unstable use of other medication; (7) current hormone therapy; (8) excessive alcohol consumption; (9) smoking; (10) elevated caffeine

intake; (11) irregular sleep-inducing work schedules; (12) inability to engage in spontaneous physical activity; (13) metabolic disorder, a sleep disorder, or a psychiatric condition; (14) pregnancy, attempts at conception, or breastfeeding; (15) use of sleep/weight supplements or medications; (16) actively intermittent fasting, are actively trying to lose weight, or have lost more than ±3 kg in previous 3 months; and (17) individuals deemed incompatible with the study protocol.

Procedures

Following preliminary screening, eligible participants provided Institutional Review Board-approved informed consent before enrollment. Participants assessed their weight and completed psychometrically validated self-report questionnaires on Day 0 (Pre), Day 30, and Day 60. Additionally, participants maintained a daily diary to document adherence and adverse events. The self-report surveys were completed *via* a secured SurveyMonkey link sent through email or text message. Each survey took ~25 min to complete at each assessment. The primary outcome was reduction in weight assessed by BodyTrace, Inc, scale. The secondary outcomes were food cravings (i.e. Food Cravings Questionnaire), mood (i.e. Profile of Mood States), anxiety (i.e. Trait Anxiety Inventory), stress (i.e. Perceived Stress Scale), and health-related quality of life (i.e. CDC Health-related Quality of Life Core Healthy Days measure). Participants were instructed to maintain their habitual lifestyle patterns and refrain from introducing new exercise, diet, or health interventions during the study. This information was collected *via* self-report. Data were collected from March 2023 to June 2023 and stored electronically. There were no changes to the trial outcomes after the trial commenced. The primary and secondary outcomes were pre-specified in the trial protocol and remained unchanged throughout the study.

Intervention

A randomized, double-blind, placebo-controlled trial design was employed. Participants were randomly assigned to either the *D. glomerata* group (DG) or the Placebo Control group (PC) for the duration of the two-month trial. The randomization process was automated using a computer-based randomization *via* SPSS. Participants were instructed to consume 300 mg/day of the allocated substance, which was an aqueous ethanol extract of *D. glomerata* fruit pods, standardized to Myricetin 1.6% and Luteolin 1.0%, supplied by Gateway Health Alliances, Inc (https://www.ghainc.com/; Fairfield, CA, USA). The supplement is a concentrated 6:1 extract of the fruit, meaning that each unit of the extract contains the equivalent of six times the amount of the dried whole fruit. The manufacturing process was as follows: *D. glomerata* fruit pods were extracted using aqueous ethanol, and the resulting solution was concentrated and dried to yield *D. glomerata* fruit pods (DYG-400®). The placebo consisted of rice protein.

Lifestyle

Participants maintained a ~2000-calorie daily diet throughout the study. Food intake and calorie content were monitored *via* a self-reported 3-day food log. Analyses indicated that the calories consumed did not change significantly over the course of the study ($p > .05$).

Adverse events

The supplement was well-tolerated, with only one adverse event reported in DG compared to two adverse events in PG. In DG, the adverse event was gastrointestinal symptoms after taking the supplement. In PG, the reported adverse events were heart palpitations and a liver concern.

Trial reporting

This trial was reported in accordance with the Consolidated Standards of Reporting Trials (CONSORT) guidelines, including the reporting of harms (Schulz et al. 2010).

Blinding

To ensure that all subjects and researchers were unaware of the treatment assignments, Gateway Health Alliances labeled the supplement/placebo bottles as either A or B. The supplement and placebo pills were identical in color, odor, and size. The research team remained blinded to the contents of the bottles until the conclusion of the study. Immediately following the last assessment, the research team was unblinded. Subsequently, participants were unblinded and informed of their assigned condition.

Supplement information and adherence

Participants were instructed to take the capsules ~30 min before a meal. Adherence was monitored by counting the number of pills remaining in the bottles. Participants also received daily text reminders to take their supplements.

Adherence

Out of 61 participants who enrolled and provided consent, 56 completed the trial, representing an adherence rate of 92%. This rate includes two dropouts from PG and three participants who withdrew due to adverse events. The reasons for dropout were obtaining a doctor-prescribed weight loss drug during the study ($n = 1$) and personal reasons unrelated to the study ($n = 1$; see Table 1 and Figure 1).

Statistical analysis

Data were analyzed for normality by examining skewness and kurtosis scores, and using the Shapiro-Wilk test and Q-Q plot. Outliers were identified as data points exceeding three interquartile ranges beyond the 25th and 75th percentiles. No extreme outliers were observed. Continuous data were presented as Mean (SD) and analyzed using 2 (Group) × 3 (Time: Baseline, Day 30, Day 60) repeated measures ANOVA. Multiple comparisons were corrected using the Sidak adjustment. Post hoc tests were paired-sample *t*-tests where applicable. Categorical variables were analyzed using the Chi-square test and expressed as counts/percentages where appropriate. Moderator analysis of gender was assessed *via* a 2(gender) a 2 (group) × 3 (Time) repeated

Table 1. Demographic data for the *Dichrostachys glomerata* group and placebo group.

Demographic variable	*Dichrostachys glomerata* group ($N=30$)	Placebo group ($N=26$)
Age	$M=44.20$ ($SD=6.97$)	$M=44.84$ ($SD=9.13$)
Body mass index	$M=31.73$ ($SD=5.55$)	$M=31.59$ ($SD=9.13$)
Number (%) Female	20 (67%)	23 (88%)
Ethnicity (number, %)		
White/Caucasian	21 (70%)	21 (81%)
Biracial	3 (9%)	1 (4%)
Asian	3 (10%)	1 (4%)
Hispanic	1 (4%)	2 (8%)
Black/African American	0 (0%)	1 (4%)
Native Hawaiian or Pacific Islander	1 (4%)	0 (0%)
Other	1 (4%)	0 (0%)

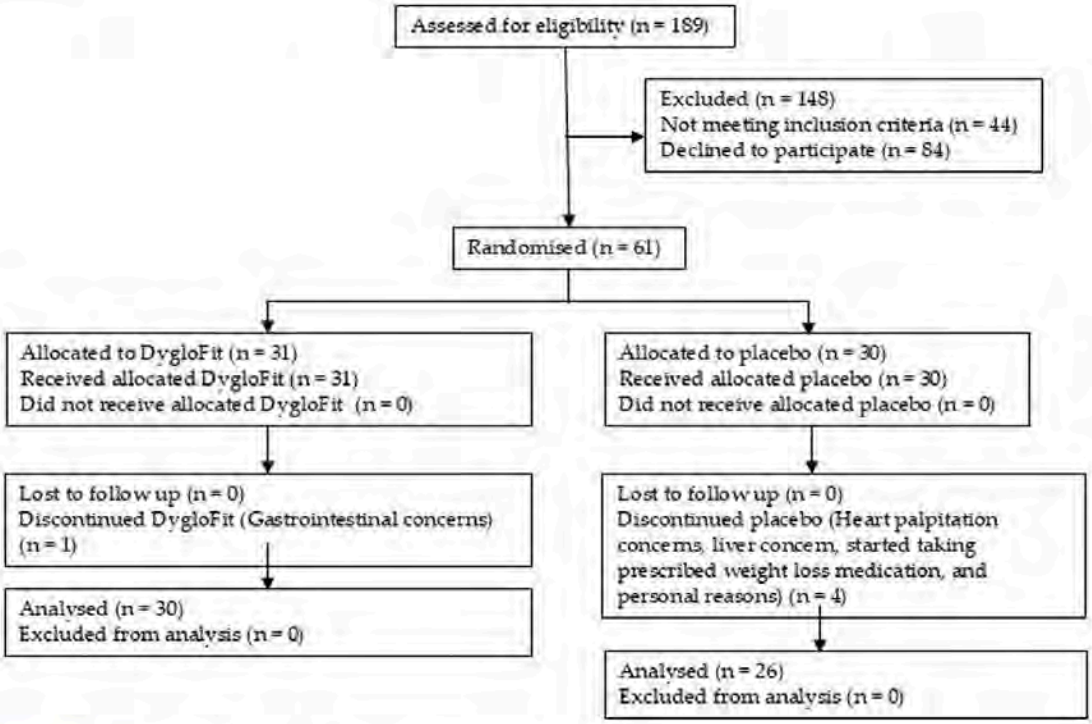

Figure 1. Participant CONSORT flow chart.

measures ANOVA. Statistical analyses were performed using Excel and Statistical Product and Service Solutions (SPSS) [version 28].

Measures

Profile of Mood States (POMS-40) Questionnaire

The POMS-40 was used to measure mood states including tension, anger, vigor, fatigue, depression, and confusion. A total mood score was computed by summing the values for tension, depression, anxiety, fatigue, and confusion, and then subtracting the vigor subscale score. The items were measured on a 5-point Likert scale ranging from 0 (not at all) to 4 (extremely). The POMS-40 has demonstrated excellent psychometric properties (McNair et al. 1992).

Trait Anxiety Inventory

The Trait Anxiety Inventory (20 items) assesses general feelings of anxiety, such as calmness, confidence, and security (Spielberger et al. 1983). Higher scores indicate greater anxiety levels. The items are assessed on a 4-point Likert-type scale ranging from 0 (not at all) to 3 (very much so), resulting in a possible score range of 0–60. The inventory has demonstrated strong psychometric properties, including high internal consistency and test-retest reliability.

Weight

Participants' weight was assessed using a smart scale (BodyTrace, Inc.), which transmitted weights directly to BodyTrace servers *via* the cellular network. The BodyTrace scale has a stated accuracy of 0.1 kg and demonstrates excellent concordance with weights measured during in-person assessment visits (Ross and Wing 2016). Weight data were downloaded from the BodyTrace servers at the end of the intervention. Additionally, participants' self-reported weights were collected *via* the intervention webserver. Weights from both the smart scale and the study website were recorded in pounds (lbs). Research supports excellent agreement between weights measured *via* smart scales (i.e. electronic scales), self-reported weights, and objective measures (Krukowski and Ross 2020).

Dietary assessments

Nutrition was assessed through a 3-day diet record. Participants recorded all food and beverage intake for three full days (two weekdays and one weekend day). The data were inputted into nutrient analysis software to compile reports for total dietary intake and pertinent macro and micronutrient information.

Food Cravings Questionnaire

The Food Cravings Questionnaire was used to assess food cravings. Items were rated on a 6-point Likert-type scale ranging from 1 (never/not applicable) to 6 (always). The questionnaire assesses various aspects of food cravings, including planning to eat, positive reinforcement from eating, relief from negative mood by eating, lack of control over eating, thoughts about food, physiological state, emotions involved during food cravings or eating, environmental cues that may trigger food cravings, and guilt experienced due to food craving. Higher scores indicate greater food cravings. Scores on the Food Cravings Questionnaire have been found to be positively associated with eating pathology, body mass index (BMI), low dieting success, and increases in the state of food craving during cognitive tasks involving appealing food stimuli (Meule et al. 2014).

Health-Related Quality of Life (HRQoL)

The CDC Health-related Quality of Life Core Healthy Days measure was used to assess health-related quality of life (CDCP 2020). The Core Healthy Days module contains

one item asking respondents to rate their general health on a 5-point scale (1 = excellent, 3 = good, 5 = poor). The module also includes three items asking respondents how many days in the past month their physical health was not good, their mental health was not good, and their health interfered with their daily activities (scores range from 0 to 30 days). This scale has excellent psychometric properties (Zack 2013).

Perceived Stress Scale

The Perceived Stress Scale-4 measures how participants perceive situations as stressful (Cohen et al. 1983). The scale assesses the degree to which people felt their life was unpredictable, uncontrollable, and overloaded during the previous month. The scale has four items rated on a 5-point Likert scale ranging from 0 (never) to 4 (very often), with higher scores indicating more perceived stress. This scale has excellent psychometric properties (Du et al. 2023).

Daily diary

The daily diary was used to assess adverse events and adherence.

Results

Weight loss and food cravings

For weight loss, a significant main effect for Condition, $F(1,54) = 9632.51$, $p < .001$, and interaction, $F(2,218) = 2.79$, $p = .05$, but no significant main effect for time were evidenced, $F(2,218) = 0.69$, $p = .50$. DG lost significantly more weight at Day 60 compared to PG. DG lost 4.11 lbs at Day 60 compared to 2.19 lbs for PG (see Figure 2). For calories consumed a significant main effect for Condition, $F(1,54) = 5912.15$, $p < .001$, but not time, $F(2,108) = 1.32$, $p = .27$, or interaction, $F(2,108) = 0.34$, $p = .71$, were evidenced. PG consumed significantly less calories than DG group, $p < .05$.

For the Food Cravings Questionnaire, significant Condition, $F(1,262) = 7472.83$, $p < .001$, Time, $F(1,262) = 3.97$, $p < .001$, and Interaction were evidenced, $F(1,262) = 1.66$, $p = .01$ (see Table 1). DG had significant reductions in food cravings from Baseline to Day 30 and Day 60 compared to PC.

Mood, anxiety, and stress

For the POMS, a significant main effect for Condition, $F(1,54) = 382.78$, $p < .001$, and Time, $F(1,54) = 382.78$, $p < .001$, as well as a significant Interaction, $F(2,108) = 4.26$, $p = .017$, were evidenced. The POMS scores improved significantly from Baseline to Day 60 for DG compared to PG (see Table 2).

For anxiety, significant main effects for Time, $F(2,108) = 7.56$, $p < .001$, and Condition, $F(1,54) = 2905.34$, $p < .001$, were evidenced. The interaction was nonsignificant, $F(2,108) = 0.52$, $p = .59$. Anxiety decreased significantly from Baseline to Day 60 for DG and from Baseline to Day 30 PG. DG also had a larger improvement in anxiety from Baseline to Day 60 compared to PG, albeit nonsignificant.

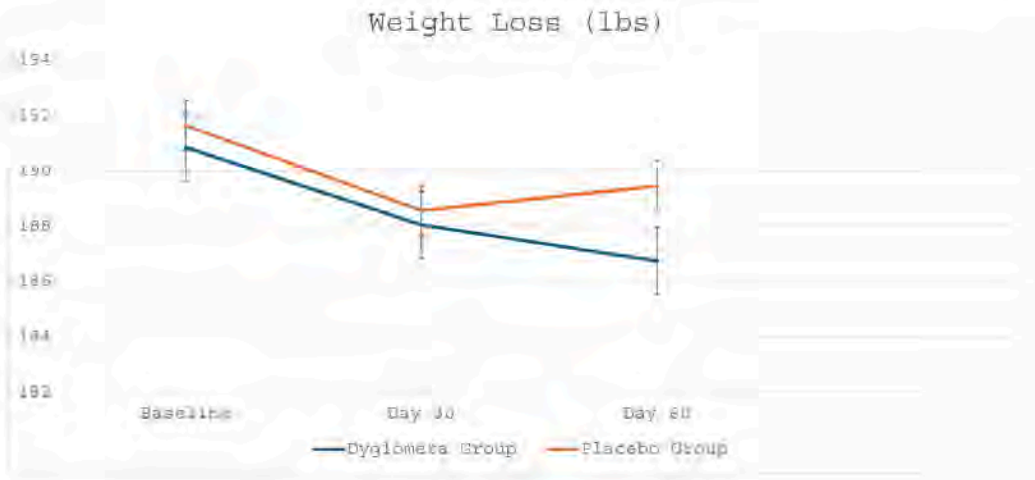

Figure 2. Weight loss (lbs) at baseline, day 30, and day 60 for the *Dichrostachys glomerata* group and placebo group. *Note: Dichrostachys glomerata* group lost significantly more weight from baseline to day 60 compared to the placebo group, $p < .05$.

Table 2. Mean (*M*) and standard deviation (*SD*) scores for the profile of mood states, trait anxiety, perceived stress scale, food cravings, weight (lbs), and calories for the *Dichrostachys glomerata* group and placebo group.

	Dichrostachys glomerata group ($N = 30$)			Placebo group ($N = 26$)		
	Baseline *M* (*SD*)	Day 30 *M* (*SD*)	Day 60 *M* (*SD*)	Baseline *M* (*SD*)	Day 30 *M* (*SD*)	Day 60 *M* (*SD*)
Profile of Mood States[†]	148.50 (8.94)	148.51 (10.55)	144.69 (9.34)[†]	149.57 (10.26)	145.16 (8.93)	149.54 (10.06)
Trait Anxiety Inventory	45.99 (8.23)	41.38 (9.69)	39.93 (8.19)[†]	46.23 (10.04)	40.45 (7.66)[†]	42.10 (9.38)
Perceived Stress Scale	5.76 (1.83)	5.12 (2.41)	4.72 (2.36)[†]	5.68 (2.07)	4.84 (2.37)	5.29 (2.41)
Weight (lbs)[‡]	190.85 (27.87)	188.04 (41.28)[†]	186.74 (45.40)[†]	191.64 (30.26)	188.56 (35.92)[†]	189.45 (35.40)[†]
Food Cravings Questionnaire[‡]	4.27 (2.01)	3.81 (1.73)[†]	3.64 (1.76)[†]	4.19 (2.16)	4.05 (2.32)	4.24 (2.92)
Calories[§]	1895.66 (504.74)	1888.46 (409.49)	1825.05 (489.72)	1863.93 (342.97)	1886.47 (419.66)	1786.94 (550.02)

Note: Lower scores indicate an improvement for the profile of mood states, trait anxiety inventory, perceived stress scale, food cravings questionnaire, and weight.
[†]Significant improvement from baseline.
[‡]Significant improvement for *D. glomerata* group *vs.* placebo group.
[§]The placebo group consumed less calories than the *D. glomerata* group.

For the Perceived Stress Scale a significant main effect for Condition $F(1,54) = 640.99$, $p < .001$ was evidenced. The main effect for Time, $F(2,108) = 2.51$, $p = .08$, and the Interaction were nonsignificant, $F(2,108) = 0.69$, $p = .50$. Perceived stress decreased significantly from Baseline to Day 60 for DG only, $p < .001$.

Health-related quality of life

For General Health, a significant main effect for Condition was evidenced, $F(1,54) = 2421.09$, $p < .001$, indicating an improvement in General Health for DG by Day 60 (see Table 3). The main effect for Time, $F(2,108) = 0.65$, $p = .53$, and the interaction, $F(2,108) = 0.12$, $p = .89$, were nonsignificant. For Physical Health significant main effects for Condition, $F(1,54) = 80.48$, $p < .001$, and Interaction, $F(2,108) = 5.28$, $p = .006$, but no significant effect for Time was evidenced, $p = .97$. Physical health scores improved significantly for DG when compared to PG at the Day 60 timepoint. DG physical

Table 3. Mean (*M*) and standard deviation (*SD*) scores for the health-related quality of life outcomes for the *Dichrostachys glomerata* group and the placebo group.

	Dichrostachys glomerata group (*N* = 30)			Placebo group (*N* = 26)		
	Baseline *M* (*SD*)	Day 30 *M* (*SD*)	Day 60 *M* (*SD*)	Baseline *M* (*SD*)	Day 30 *M* (*SD*)	Day 60 *M* (*SD*)
General health	3.07 (0.69)	3.18 (0.65)	3.21 (0.62)†	3.04 (0.60)	3.12 (0.6)	3.09 (0.63)
Physical health‡	3.53 (3.35)	4.03 (4.67)	2.34 (3.10)†	2.21 (2.34)	1.55 (1.57)	3.52 (4.42)
Mental health‡	5.09 (3.63)	5.51 (5.28)	3.80 (4.20)†	6.41 (5.25)	3.52 (3.65)†	5.51 (5.09)
Poor mental or physical health prevented activities‡	2.70 (3.27)	2.37 (2.05)	1.52 (1.88)†	2.67 (2.59)	1.11 (1.77)†	2.11 (2.15)

Note: Higher scores = improvements for general health. For all other items a lower score indicates an improvement.
†Significant improvement from baseline.
‡Significant improvement for *Dichrostachys glomerata* group *vs.* placebo group.

health improved from Baseline to Day 60 compared to worsening for PG, $p < .05$. As well, for Mental Health significant main effects for condition, $F(1,54) = 131.90$, $p < .001$, and interaction, $F(2,108) = 3.78$, $p = .02$, were evidenced; but no significant time effect, $F(2,108) = 1.67$, $p = .19$, was found. DG mental health improved significantly from Baseline to Day 60 compared to PG, $p < .01$. PG mental health improved significantly from Baseline to Day 30, $p < .05$.

For poor mental or physical health preventing activities significant main effects for Condition, $p < .001$, and Interaction, $p = 01$, and Time, $p = 0.50$, were evidenced for DG compared to PG. DG scores improved significantly compared to PG by Day 60, $p < .05$. In comparison PG had a significant worsening in the number of days that pain made activities difficult from Baseline to Day 60, $p < .05$.

Moderator analysis

Moderator analysis by gender revealed no gender effects, $p's > .05$.

Discussion

The purpose of this study was to assess the impact of DYG-400®, a standardized powder derived from the aqueous ethanol extraction, concentration, and drying of *D. glomerata* fruit pods, on weight loss and health-related outcomes in overweight and mildly obese adults. *Dichrostachys glomerata* fruit pods (DYG-400®) have previously demonstrated anti-inflammatory properties and the capacity to regulate fat metabolism in both animal models and obese individuals with metabolic syndrome (Etoundi et al. 2010; Kuate et al. 2010, 2011, 2013; Dieudonne et al. 2013). Using a randomized double-blind placebo-controlled trial, we found that 60 days of supplementation with *D. glomerata* fruit pods (DYG-400®) resulted in significant improvements in weight loss, food cravings, HRQoL, and mood for the DG compared to the PG. Additionally, anxiety and perceived stress improved from Baseline to Day 60 for the DG. Study findings, limitations, and proposed future research directions are discussed below.

Weight loss and food cravings

The DG lost significantly more weight at Day 60 compared to the PG, with the DG losing 4.11 lbs compared to 2.19 lbs for the PG. Interestingly, the DG lost more weight despite the PG consuming significantly fewer calories. Regarding food cravings, the DG showed significant reductions from Baseline to Day 30 and Day 60 compared to the PG. Previous research has found that reduced food cravings are associated with greater long-term weight loss (Dalton et al. 2017). Future studies should examine the longer-term effects of *D. glomerata* supplementation on food cravings and weight loss beyond 60 days. Additionally, multidimensional assessments of food cravings are encouraged to understand which factors are most influenced by supplementation. Identifying individuals who frequently experience food cravings and overeats in response may improve treatment and prevention strategies, as these individuals are more susceptible to weight gain and less successful in weight loss and management.

Laboratory research has shown that *D. glomerata* inhibits adipogenesis and lipogenesis by regulating AMPK phosphorylation in white adipose tissues and 3T3-L1 adipocytes, and promotes lipolysis by increasing the expression of lipolysis-related proteins (Kim et al. 2022). These results suggest that *D. glomerata* can be an effective dietary supplement for treating obesity due to its modulating effects on adipogenesis, lipogenesis, and lipolysis. Our results provide randomized controlled trial evidence supporting the effectiveness of *D. glomerata* as a natural supplement to aid in weight loss and reduce associated food cravings.

Health-related quality of life

Consistent with other research (Fontaine et al. 2003), we found that weight loss was associated with improved HRQoL. Our findings revealed that as little as 4 lbs of weight loss resulted in improved HRQoL, addressing a needed research direction (Williamson et al. 2000; Kolotkin and Andersen 2017). Specifically, the DG had significant improvements compared to the PG by Day 60 in general health, physical health (including physical illness and injury), mental health (including stress, depression, and emotional problems), and poor mental or physical health preventing activities, such as self-care, work, or recreation. Conversely, the PG showed a significant worsening in the number of days that pain made activities difficult from Baseline to Day 60.

Mood, anxiety, and stress

For mood (POMS), the DG significantly improved from Baseline to Day 60 compared to the PG. The POMS measures the mood states of tension, anger, vigor, fatigue, depression, and confusion. Anxiety decreased significantly from Baseline to Day 60 for the DG and from Baseline to Day 30 for the PG. Although the DG showed a larger improvement in anxiety from Baseline to Day 60 compared to the PG, this was nonsignificant. Perceived stress decreased significantly from Baseline to Day 60 for the DG only, suggesting a potential stress-reduction effect associated with *D. glomerata* supplementation.

Safety, generalizability, and significance

Over-the-counter herbal preparations for treating excess weight have limited data documenting their efficacy or safety (Bray et al. 2018; Batsis et al. 2022). Our study provides much-needed data indicating the safety and effectiveness of this supplement in overweight and mildly obese adults. Consistent with animal and lab tests (Kothari et al. 2014), *D. glomerata* was found to be safe and well-tolerated by participants. Only one minor adverse event was reported in the DG (i.e. gastrointestinal issues). While the placebo of rice protein is generally well-tolerated, two participants in the PG reported adverse effects, possibly due to rare cases of gastrointestinal discomfort or allergies. The nocebo effect may also have contributed to these reports. Future studies should consider potential sensitivities to rice protein and explore alternative placebo options to reduce such occurrences. Our results can be generalized to similar weight and age groups. Further research is needed in a variety of populations (e.g. varying ages and weights) to establish the generalizability of these results in both clinical and nonclinical populations.

Herbal supplements are gaining prominence in contemporary healthcare due to their potential to enhance overall health outcomes, reflecting a broader trend toward integrative and complementary medicine (Hassen et al. 2022). Historically rooted in traditional healing systems, recent studies have begun to validate the efficacy of these supplements in supporting various physiological and psychological functions, including immune health, cognitive performance, mood regulation, and metabolic balance. For instance, recent research highlights the benefits of dietary supplements in areas, such as pain management (Grifell et al. 2024; Retno et al. 2024), nonalcoholic fatty liver disease (Ghoreishi et al. 2024), and atopic dermatitis (Meysami et al. 2021). This growing interest in herbal alternatives is largely driven by patient preferences for holistic and preventative approaches, alongside a desire to avoid the side effects commonly associated with pharmaceuticals. Additionally, the increasing focus on personalized health and wellness has accelerated the demand for supplements that cater to specific health needs, particularly among an aging population and those prioritizing preventative care. To fully realize the benefits of herbal supplements, rigorous clinical research is essential to establish standardized dosages, safety profiles, and long-term efficacy. Integrating these supplements into broader healthcare strategies could provide more personalized, patient-centered care, enhancing both preventive and therapeutic outcomes.

Study limitations

This study has several limitations that should be considered. The 60-day duration limits our ability to assess the long-term effects of *D. glomerata* (DYG-400®) on weight loss and health outcomes, necessitating future studies with extended follow-ups. More detailed objective tracking of caloric intake, such as through digital food diaries or calorimetry, would provide a more accurate assessment of dietary adherence and its potential impact on weight loss, reducing the reliance on self-reported data and minimizing reporting bias. The sample size, though sufficient for the study's primary outcomes, may have been inadequate for subgroup analyses, and the reliance on self-reported measures introduces potential biases. Additionally, the study's findings are specific to overweight and mildly obese adults, limiting generalizability to more diverse populations. While DYG-400® was well-tolerated, more comprehensive safety

assessments, especially regarding long-term use and interactions with other treatments, are needed to further establish its safety profile.

Conclusion

In summary, this study examined the efficacy of *D. glomerata* fruit pod powder on overweight and mildly obese adults in a double-blind, placebo-controlled trial. The results revealed that *D. glomerata* fruit pod supplementation led to significant weight loss, reduced food cravings, improved mood, and decreased anxiety and perceived stress levels, leading to enhanced quality of life. These preliminary findings suggest the potential of *D. glomerata* as a beneficial supplement for weight management and overall well-being. Further research with larger sample sizes is needed for a comprehensive understanding of its mechanisms and long-term effects.

Author contributions

HAH and SLH designed research; HAH, SLH, TAL, SMB, and TLB conducted research; HAH and SLH analyzed data; and HAH and SLH wrote the paper. HAH had primary responsibility for final content. All authors read and approved the final manuscript.

Disclosure statement

No potential conflict of interest was reported by the author(s).

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Data availability statement

Data and/or statistical analyses are available upon request on a case-by-case basis for noncommercial scientific inquiry and/or educational use as long as Institutional Review Board restrictions and research agreement terms are not violated.

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