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Effectiveness of an African spice fruit on weight, mood, and health-related quality of life

Submission date 08/12/2023	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 11/12/2023	**Overall study status** Completed	
Last Edited 24/09/2024	**Condition category** Other	

Plain English summary of protocol
Background and study aims
This study aimed to investigate the effects of a herbal product called Dyglomera® made from Dichrostachys glomerata fruit pods

Who can participate?
Overweight and mildly obese adults aged 25 - 60 years

What does the study involve?
Participants were randomly divided into two groups, one receiving Dyglomera® and the other a placebo. They were assessed for weight, food cravings, mood, and quality of life over 60 days.

What are the possible benefits and risks of participating?

Where is the study run from?
Wellness Discovery Labs (USA)

When is the study starting and how long is it expected to run for?
November 2022 to June 2023

Who is funding the study?
Gateway Alliances (USA)

Who is the main contact?
Prof Heather Hausenblas, hhausenblas@wellnessdiscoverylabs.com

Contact information

Type(s)
Public, Scientific, Principal investigator

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Study information

Scientific Title
Effectiveness of African spice fruit (Dichrostachys glomerate) supplementation on overweight and mildly obese adult's weight, mood, and health-related quality of life: a randomized double-blind placebo-controlled trial

Study objectives
The purpose of this study was to investigate the weight, food cravings, mood, and health-related quality of life effects of Dyglomera® on overweight and mildly obese adults

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 11/11/2022, Sterling IRB (6300 Powers Ferry Rd Suite 600-351, Atlanta, 30339, United States of America; +1 888-636-1062; support@sterlingirb.com), ref: 10504-HAHausenblas

Study design
Randomized double blind placebo controlled trial

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Treatment of overweight and mild obesity

Interventions
This study was conducted in a double-blind, parallel treatment, stratified random, placebo-controlled manner. The independent variable was the Dichrostachys glomerata nutritional supplementation. The dependent variables were body weight (primary outcome) and food

cravings, mood, anxiety, stress, and health-related quality of life (secondary outcomes). Sample size power calculation indicated that 35 participants were needed in each group to achieve a power of 80% and alpha < .05 (https://clincalc.com/stats/samplesize.aspx).

Procedures: Following preliminary screening, eligible participants provided Institutional Review Board approved informed consent prior to enrolment. Participants completed psychometrically validate self-report questionnaires on Day 0 (Pre), Day 30, and Day 60. In addition, participants maintained a daily diary to document adherence and adverse events. Participants completed the self-report surveys via a SurveyMonkey link that was sent via email or text. Completion of the surveys took about 25 minutes at each assessment. Participants were instructed to maintain their habitual lifestyle patterns and refrain from introducing new exercise, diet, or health interventions during the study. These data were collected from March 2023 to June 2023 and were stored electronically.

Intervention: A randomized double-blind placebo-controlled trial design was employed, with participants randomly assigned to either the Dichrostachys glomerata group (DG) or Placebo Control Group (PC) for the duration of the two-month trial. We used a computer-based randomization via SPSS to automate the random assignment process. Participants were directed to consume 300 mg, 1/d of the allocated substance. Dyglomera®, an aqueous ethanol extract of Dichrostachys glomerata fruit pods (standardized to Myricetin 1.6% and Luteolin 1.0%), was supplied by Gateway Health Alliances, Inc (https://www.ghainc.com/; Fairfield, CA, USA). The manufacturing process was as follows: Dichrostachys glomerata fruit pods were extracted using aqueous ethanol. The resulting solution was concentrated and dried to yield Dyglomera®. The placebo was rice protein.

Intervention Type
Supplement

Primary outcome(s)
Weight (kg) measured using a smart scale (BodyTrace, Inc.), at Baseline, Day 30 and Day 60.

Key secondary outcome(s))
1. Food cravings measured using the Food Cravings Questionnaire (Meule et al., 2014) at Baseline, Day 30 and Day 60.
2. Health-related quality of life measured using the CDC Health-related Quality of Life Core Healthy Days at Baseline, Day 30 and Day 60.
3. Mood measured using Profile of Mood States (POMS) Questionnaire (McNair et al., 1992) at Baseline, Day 30, and Day 60.
4. Anxiety measured using the Trait Anxiety Inventory (Spielberger et al., 1983) at Baseline, Day 30, and Day 60.
5. Perceived stress measured using the Perceived Stress Scale-4 (Cohen et al., 1983) at Baseline, Day 30, and Day 60.

Completion date
01/06/2023

Eligibility

Key inclusion criteria
Overweight and mildly obese adults (BMI between 25.00 to 34.99 kg/m²)

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
25 years

Upper age limit
60 years

Sex
All

Total final enrolment
61

Key exclusion criteria
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 ± 3kg in previous 3 months
17. Individuals deemed incompatible with the study protocol

Date of first enrolment
02/01/2023

Date of final enrolment
04/01/2023

Locations

Countries of recruitment
United States of America

Study participating centre
Wellness Discovery Labs
76 S Laura St
Jacksonville
United States of America
32202

Sponsor information

Organisation
Gateway Alliances

Funder(s)

Funder type
Industry

Funder Name
Gateway Health Alliances

Results and Publications

Individual participant data (IPD) sharing plan
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. Contact H. Hausenblas at hhausen@ju.edu

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		23/09/2024	24/09/2024	Yes	No