Title: The Acute Metabolic Impacts of *Kampferia parviflora* extract in Healthy Men: A Randomized Double-Blind Proof of Concept Study

January 28, 2025

NCT:

Study Protocol

Study Design

This study followed a randomized, double-blinded, crossover design. Participants reported to the clinical site on two separate visits. Participants were instructed to abstain from exercise on testing day and arrive at the lab fasted (no food or caffeine ingestion for 4 hours prior). Testing sessions consisted of two visits per week with a minimum of 24 hours between visits. During the first visit demographics and anthropometrics were assessed. At every testing each subject completed the following protocol: baseline Metabolic Rate and Respiratory Quotient. Immediately after baseline test, participants consumed supplement 1 or 2. Metabolic Rate and Respiratory Quotient Testing was repeated at 60, 120, and 180 minutes after supplementation. All participants underwent an informed consent process in accordance with the Declaration of Helsinki and an approved IRB protocol approved by institutional review board at Nova Southeastern University, IRB number 2024-209.

Metabolic and Respiratory Quotient Testing

An indirect calorimetry device (Parvo Medics TrueOne 2400) was used to measure RMR and RQ. The device was calibrated according to the manufacturer's instructions. Participants were instructed to lay completely still and relax for 15 minutes. The first 5 minutes was allotted for acclimatization. The Parvo Metabolic Cart measures the volume of oxygen consumed (VO_2) and the volume of carbon dioxide produced (VCO_2) by the patient on a breath-by-breath basis. The ratio of these gases is used to determine the Respiratory Quotient (RQ), providing information regarding substrate utilization. The parameters that were measured and used for analysis were RMR, O_2 volume (VO_2), CO_2 volume (VCO_2), the RQ, percentage of utilized fat (Fat%), and percentage of utilized carbohydrates (CHO%).

Statistical Analysis

All data is expressed as mean SD. Basic descriptive statistics were used for participant demographics and anthropometrics. A paired t-test was used to assess any differences between the 100 and 200 mg doses for REE and RER at baseline. To determine the effects of Gyngerlean™ on energy expenditure, a repeated-measures analysis of variance (ANOVA) was used to determine differences between 100mg and 200mg doses for the 60, 120- and 180-time intervals. A repeated Dunnett's multiple