

Acute Effect of Melon Manis Terengganu Peel
Powder on Glycemic Response, Satiety, and Food
Intake in Adults at Risk for Type 2 Diabetes

NCT05298111

25 March 2022

Study Protocol

Open-label, randomised, placebo-controlled, crossover study with two intervention arms. The study was conducted in 30 participants and the primary objective is to show an improved glycemic response after Melon Manis Terengganu (MMT) peel powder consumption in people at risk of type 2 diabetes. Besides, the acute effect of MMT peel powder on perceived satiety and energy intake were explored.

Pre-test protocol

Participants were required to obtain adequate sleep (7 to 9 hr) on nights before test days (Hirshkowitz et al., 2015). They were instructed by the researchers to maintain their usual daily food intake and consume a dinner of similar composition and quantity at a similar time before their study visit besides avoiding caffeine consumption such as caffeinated beverages, meals or medications as well as alcohol consumption. This is to minimize within-respondent variability (Al-Mana & Robertson, 2018) as well as ensure similar feelings of satiety and glycemic response on study visits (Kay, 2016). Additionally, participants were required to avoid moderate or strenuous activity (as indicated by the IPAQ-SF) before the test days as this would deplete their glycogen content derived from the liver and muscle. Glycogen can be stored for up to 12 to 48 hr, after which the body switches to oxidative fats and ketones metabolism (Lean, 2015).

To ensure that these habits had not been modified during the study, the participants were instructed to record 24-hr dietary recalls (food logs) and physical activity diaries (IPAQ-SF) as well as take photos of any food and drinks they consumed which were reviewed by the researcher on the test days to ensure accuracy and completeness. Any unclear aspect was clarified on the spot. A copy of the food log was kept by the participants for them to refer back to each study visit to preserve meal accuracy, especially dinner meals consumed before each visit.

They were required to fast for 10 to 12 hr preceding their testing time and hence they were instructed to eat their dinner no later than 10 pm. They were only allowed to consume plain water once their testing period began. The pre-test protocols were no longer in effect once participants finished their testing for the day, and they were free to resume their normal activities and food habits.

Data collection

Participants attended the lab at 8 am with light clothing and were asked a series of questions to measure fasting, nutrition, physical activity and sleep regimen adherence. They were also required to hand in the completed questionnaire which consisted of dietary and physical activity information which were distributed to them before data collection. Then, height, weight, waist circumference, % body fat and blood pressure measurement were taken followed by a perceived satiety measurement and fasting capillary blood sample (baseline) withdrawal using the finger pricking method.

After that, the participants were randomized to consume one of the two types of test products namely A: control (glucose) and B: Formulation 3 (60% sweetener) dissolved in 180 mL plain water together with the standardized breakfast in treatment sequences (AB, BA). Each respondent consumed the meals in a separate place and avoided using electronic gadgets while eating to reduce distractions. They were instructed to consume the meals at a comfortable pace within 15 min. Participants were asked to remain rested in the same place during the testing period and allowed to read, use their phone or laptop and use the toilet after meals consumption. They have also refrained from excessive physical activity until the end of test visit.

At the first bite, a timer was started and postprandial blood samples as well as perceived satiety measurement were then taken at 30, 60, 90 and 120 min thereafter. Blood collection techniques adhered exactly as they were written in the standard operating procedure (SOP). After the 120 min assessments, participants were allowed to leave the testing site and instructed to record the food consumed for the rest of the day. The food record was aimed to explore the changes in food intake following each test food relative to usual food intake (baseline data) (Burton-Freeman et al., 2017). Also, they were given a new food log form and physical activity diary to fill in one day before the next study visit. Figure 3.4 displayed the study flow chart.