

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

NCT05298111

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Statistical Analysis Plan (SAP)

Data Checking and Normality Test

Data entry errors and respondent's errors may occur during data entry and answering the questionnaire. Data were checked after they were entered into the SPSS. Data checking was crucial to ensure the accuracy of all the entered data, identify any missing data and any outliers during the data entry. Mistyping responses or entering data was an example of data entry errors in contrast to respondent's errors that happened during answering the questionnaire, for example the participants did not complete the questions or provide an unreadable or illogical response.

Before descriptive statistical analysis was performed, the frequency distribution (histogram) and boxplot were used for checking normality visually. Normally distributed population generated a bell-shaped curve appearance of the histogram with symmetrical about the mean indicates data. Besides, the Shapiro-Wilk test was done for the assessment of normality tests and the data considered to be normal if $p > 0.05$. Hence, according to the findings, the data checkinwas g revealed that all the variables have completed 30 valid frequencies for socio-demographic, anthropometry, biochemical, blood pressure, dietary intake, perceived satiety and physical activity information. Those outputs implied that no missing data value was reported.

Statistical Analysis

The data were analysed by using IBM SPSS system version 21.0 and Nutritionist ProTM software (Version 7.0.0, Axxya Systems).

Descriptive Statistic

A descriptive statistic was used to present all outcomes on socio-demographic information, anthropometric measurement, blood glucose levels, blood pressure measurement, dietary intake, perceived satiety and physical activity. Continuous data were described as mean \pm standard deviation if normally distributed or median (interquartile range) if not normally distributed meanwhile for categorical variables, the data were reported as the number of frequency and percentage. The 2 hr area under the curve (AUC) of blood glucose levels (incremental area above the baseline value) and perceived satiety (hunger, fullness, desire to

eat, prospective food consumption and thirstiness) were calculated using the trapezoidal approximation (Winham et al., 2017). The maximum concentration (C_{max}) of blood glucose levels were taken to be the highest concentration within the respective time interval (Stewart & Zimmer, 2017).

Nutritionist Pro was a dietary analysis software used for macronutrient and micronutrient analysis. This software consists of several food databases including the USDA Food Database, Canadian Food Database, Mexico Food Database and the Malaysian Food Composition Tables along with other hundreds of international food items. In this software, if the food item consumed by the participants was not available, the researchers can readily substitute it with other identical food items available in the databases. Besides, the standard recipe was created for food products that could not be found in any of the previously mentioned sources. The dietary intake of the participants for habitual, pre-test and test day were inserted in the software, and subsequently, the interested macronutrients (energy, carbohydrate, protein, fat, and dietary fibre) or micronutrients (calcium, magnesium, zinc, iron, selenium, Vitamin A, E, K, and C) were conveyed to SPSS for further analysis.

Bivariate and General Linear Model Analysis

A paired t-test (normally distributed) or Wilcoxon matched pair signed-rank sum test (non-normally distributed) was used to compare the difference of two data between groups (placebo and intervention) on anthropometric measurements, blood glucose levels (iAUC and C_{MAx}), blood pressure, dietary intake, physical activity and perceived satiety (AUC). Two-way repeated measures ANCOVA was used to compare the postprandial blood glucose levels between two test products over different time points, controlling for treatment and time to test for treatment by time interaction after adjustment for covariates (age, ethnicity, gender and BMI) (Tongyu & Chong-Do, 2021; J. Wang et al., 2021). Rather than subtracting from baseline data alone, including baseline data as a covariate will improve the analyses' performance. Furthermore, due to random deviations at baseline, the use of baseline subtraction can result in artefactual effects (whether these differences are statistically significant or not) (Blundell et al., 2010). The perceived satiety was analysed using the Friedman non-parametric test. The analysis was considered significant at a p -value ≤ 0.05 . Any significant data was further tested using Wilcoxon matched pair signed-rank sum test.