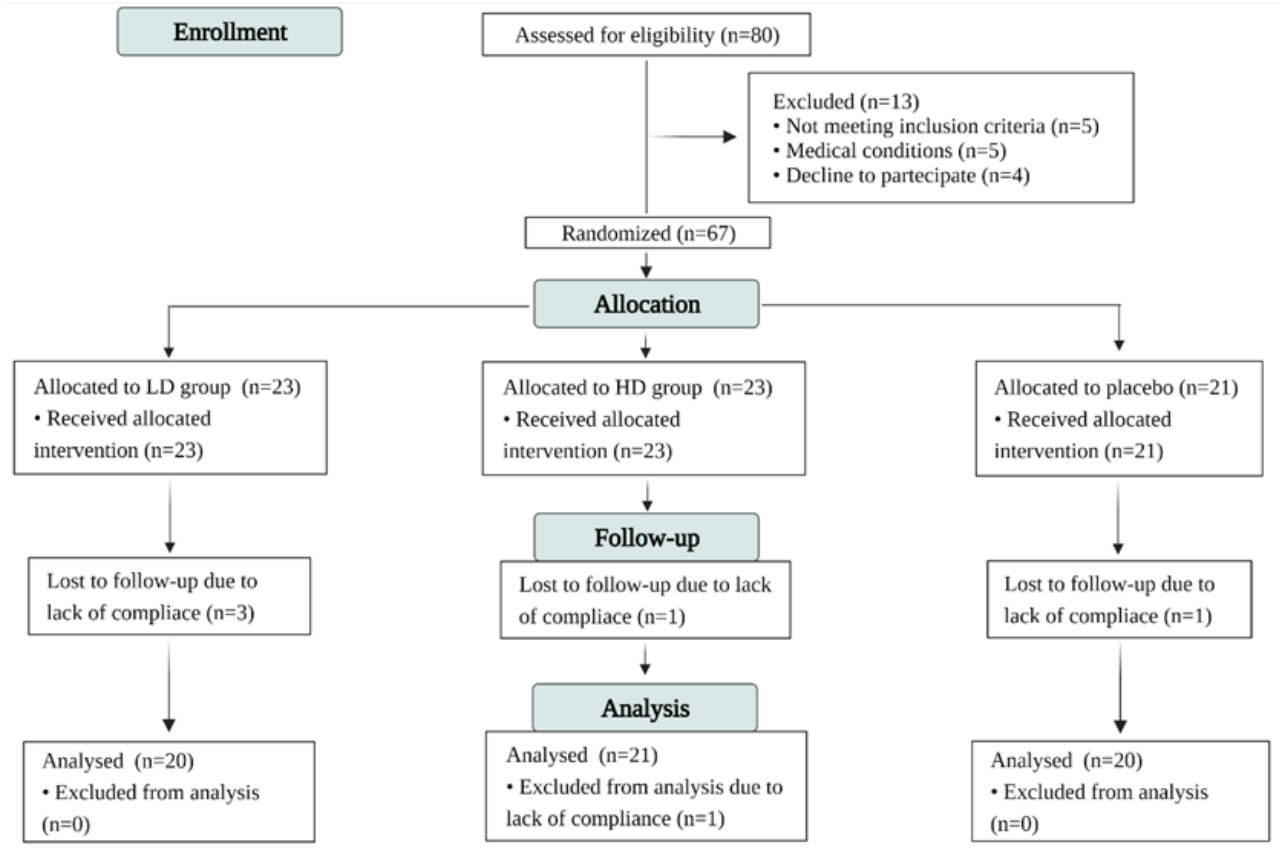
Study record 41976

STUDY POPULATION AND DESIGN

Study participants were recruited by the Samnium Medical Cooperative (Sant'Agata De' Goti, Italy). Patients were enrolled in May 2019. Protocol, letter of intent of volunteers, and synoptic documents about the study were submitted to the Scientific Ethics Committee of AO Rummo Hospital (Benevento, Italy). The sample size was calculated using G*Power 3.1.9.4 statistical analysis software to achieve 80% power. Patients aged 18–83 years with T2DM, as defined by the American Diabetes Association, for more than one year were eligible for enrolment. Figure 1 shows the flow of participants through the trial according to the criteria recommended in the CONSORT guidelines. A total of 80 T2DM were initially invited to participate. Exclusion criteria were: type 1 diabetes mellitus (T1DM), smoking, hepatic disease, renal disease, heart disease, drug therapy or supplement intake containing ABA or polyphenols, heavy physical exercise (> 10 h/week), underweight (Body Mass Index < 18.5 kg/m2), pregnant women, women suspected of being pregnant, women who hoped to become pregnant, breastfeeding, use of vitamin/mineral supplements 2 weeks before starting the study, birch pollen allergy, and donation of blood less than 3 months before the study. The occurrence of any of the above exclusion criteria during the trial resulted in the immediate cessation of participation in the study seven patients did not qualify for the study due to improper inclusion/exclusion criteria. Finally, a total of sixty-seven patients received allocated intervention, and sixty-one of them completed the study. Participants received oral and written information concerning the study before they gave their written consent.

Figure 1. Study Consolidated Standards of Reporting Trials (CONSORT) flow diagram.



Abbreviations. HD, high doses of thinned nectarine group; LD, low doses of thinned nectarine group.

This study was designed as a 12-week, monocentric, double-blind, randomized, placebo-controlled, 3-arm parallel-group trial. Patients were randomly allocated to three intervention groups: placebo (PL) group (500 mg of maltodextrins three times/day), low dose of TN (LD) group (500 mg of TN three times/day, lyophilized), or high dose of TN (HD) group (750 mg of TN three times/day, lyophilized). Both placebo and TN treatments were self-administered as tablets. Treatment compliance was assessed by counting the number of tablets returned at the time of specified clinic visits. Throughout the study, we instructed patients to take their first dose of new medication on the day after they were given the appropriate treatments. All treatments were provided free of charge. Randomization was done using a drawing of envelopes containing randomization numbers. The random number list was generated by an investigator with no clinical involvement in the trial. Patients, core laboratories, clinicians, and trial staff were blind to treatment allocation. Periodic and standardized telephone interviews were performed by qualified personnel in order to verify and increase protocol compliance.

ASSESSMENTS

At the study start, all patients underwent a standardized physical examination, assessment of medical history (for up to five years before enrolment) and of vital signs (blood pressure and heart rate, laboratory examination, measurements of body height, body weight, and waist circumference (WC), with the evaluation of Body mass index (BMI). BMI was calculated from body height and body weight. Blood samples were collected after 12 h of fasting at weeks 0, 4, 8, and 12 in 10-mL EDTA coated tubes (Becton Dickinson, Plymouth, United Kingdom), and plasma was immediately isolated by centrifugation (20 min, 2.200 g, 4°C). All samples were stored at −80°C until analysis. Subjects were asked to abstain from alcohol consumption and practice hard physical activity 48 h prior to blood sampling. Plasma total cholesterol (TC), high-density lipoprotein-cholesterol (HDL-C), low-density lipoprotein-cholesterol (LDL-C), fasting plasma glucose (FPG), triglyceride (TG), aspartate aminotransferase (AST), alanine aminotransferase (ALT), and creatine levels were determined using commercially available kits from Diacron International (Grosseto, Italy). Analyses were performed on a Diacron International Free Carpe Diem. Glycated hemoglobin (HbA1c) was determined with a commercially available kit (InterMedical s.r.l, Italy). Fasting plasma insulin (FPI) was measured using an enzyme-linked immunosorbent (ELISA) assay commercial kit (InterMedical s.r.l, Italy). Homeostatic model assessment of insulin resistance (HOMA index) was calculated with the formula: FPG (mg/dl) times FPI (μUI/ml) divided by 22.5.

STATISTICS

Unless otherwise stated, all the experimental results were expressed as the mean ± standard deviation (SD). Statistical analysis of data was performed by the Student's t-test or Pearson's correlation test. P-values less than 0.05 were regarded as statistically significant. The degree of the linear relationship between two variables was measured using the Pearson product-moment

correlation coefficient (R). Correlation coefficients (R) were calculated using GraphPad Prism 8.4.3.