

Abstract

Effects of a Diabetes-Specific Formula on Glycemic Control and Cardiometabolic Risk Factors in Overweight and Obese Adults with Type 2 Diabetes: Results from a Randomized Controlled Trial [†]

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Abstract: Lifestyle modification, including nutrition therapy, plays an important role in diabetes management. The objective of this randomized controlled trial was to investigate the effects of a diabetes-specific formula (DSF) on glycemic control and cardiometabolic risk factors in individuals with type 2 diabetes. A total of 251 adult men and women with type 2 diabetes on oral anti-hyperglycemic medication(s) were enrolled, and 235 were randomly assigned to one of two study treatments: (i) DSF with standard of care (DSF group) ($n = 117$) or (ii) standard of care alone (control group) ($n = 118$). The DSF group was asked to consume either one serving of DSF (if baseline BMI ≥ 23.0 and <27.5 kg/m²) or two servings of DSF (if baseline BMI ≥ 27.5 and <35.0 kg/m²) as a meal replacement (MR) or partial MR. Blood biomarkers, anthropometry, body composition, and blood pressure were assessed at baseline, day 45, and day 90. Mean (SE) HbA1c of participants was 7.94 (0.05)% and BMI was 28.37 (0.21) kg/m² at baseline. The DSF group had a significantly greater reduction in HbA1c than the control group at day 45 (-0.44% vs. -0.26% ; $p = 0.015$) and day 90 (-0.50% vs. -0.21% ; $p = 0.002$). Fasting blood glucose was significantly lower in the DSF group at Day 90 (-0.14 mmol/L vs. $+0.32$ mmol/L; $p = 0.036$). The DSF group lost twice as much weight as the control group at day 45 (-1.30 kg vs. -0.61 kg; $p < 0.001$) and day 90 (-1.74 kg vs. -0.76 kg; $p < 0.001$). Waist circumference, hip circumference, fat mass, and visceral adipose tissue were significantly lower in the DSF group compared to the control group (all overall $p \leq 0.004$). The DSF group also had significantly lower diastolic blood pressure (overall $p = 0.045$) and systolic blood pressure at day 90 ($p = 0.043$). This study demonstrated that consuming DSF as a MR or partial MR in addition to the standard of care resulted in significantly greater improvements in glycemic control and cardiometabolic risk factors in overweight and obese adults with type 2 diabetes compared to the standard of care alone.

Keywords: type 2 diabetes; nutrition therapy; meal replacement; diabetes-specific formula; glycemic control; body composition; cardiometabolic risk factors



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