

A Randomized Clinical Trial to Compare a Precision Nutrition Intervention Targeting a Reduction in Postprandial Glycemic Response to Meals With a Low-Fat Diet for Weight Loss

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Objectives: The primary aim is to compare the effects of a low-fat diet vs a personalized diet on % weight loss at 6-months. Secondary outcomes include body composition (fat mass [FM] and fat free mass [FFM]), resting energy expenditure (REE) and adaptive thermogenesis (AT).

Methods: The Personal Diet Study was a 6-month, single-center, randomized clinical trial in adults with pre-diabetes and moderately controlled type 2 diabetes who were overweight or obese. Participants were randomized to follow either a hypocaloric low-fat diet, with < 25% energy intake from total fat (*Standardized*), or a hypocaloric personalized diet determined by a machine learning algorithm which predicts PPGR to meals (*Personalized*). Participants in both arms

received behavioral counseling and logged dietary intake and physical activity into a smartphone app. Participants in the *Personalized* arm received real-time feedback as color-coded scores based on pre-consumed meals entered into the smartphone app. T-tests were used to assess group differences.

Results: A total of 200 adults (*Standardized*: n = 97 vs. *Personalized*: n = 103) contributed data (mean [SD]: age, 58 [11] years; 67% female; BMI, 34.0 [4.8] kg/m²; HbA1c, 5.8 [0.6]%; Metformin use, 21.0%). There were no significant group differences in mean % weight loss (*Standardized*: -4.4 [4.8]% vs *Personalized*: -3.3 [5.4]%; p = 0.19), mean absolute change in FM (*Standardized*: -2.7 [3.4] kg vs. *Personalized*: -1.6 [3.5] kg; p = 0.18), and AT between the two arms (*Standardized*: -54.7 [177] kcal/d vs. *Personalized*: 26.2 [199] kcal/d; p = 0.078). However, the *Standardized* arm lost significantly more FFM (-1.4 [1.6] kg vs. -0.45 [2.0] kg; p = 0.03) and had a greater decrease in REE (-111.0 [195.0] kcal/d vs. 1.93 [215.0] kcal/d; p = 0.02) compared to *Personalized*.

Conclusions: A personalized diet to minimize PPGR had no greater effect on % weight loss compared to a low-fat diet at 6-months. Future precision nutrition trials may require deeper phenotyping of individuals or the development of body weight-specific algorithms.

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