

Effects of a Low-Carbohydrate Dietary Intervention on Hemoglobin A1c: A Randomized Clinical Trial.

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Background

More than 37 million people have diabetes, 90-95% of those cases are type 2.¹ Additionally, an estimated 96 million adults have prediabetes.² Evidence supports the role of healthy diets and intensive lifestyle changes, specifically diet and exercise, to help manage blood sugar.³ Interventions that lower A1c have demonstrated a risk reduction in diabetes complications⁴, diabetes remission⁵ and improved metabolic outcomes⁶. Trials testing the efficacy of low carbohydrate diets in prediabetes individuals or those naïve to medications is limited.

Objective

The objective of this study was to evaluate the effect of a behavioral intervention promoting a low-carbohydrate diet compared with usual diet on 6-month change in HbA1c among individuals with elevated, untreated HbA1c.

Methods

A total of 150 adults aged 40 to 70 years with untreated type 2 diabetes who had a HbA1c of 6.0% to 6.9% (42-52 mmol/mol), were enrolled in the study. Individuals with Type 1 diabetes and those using glucose lowering medications were excluded. Recruitment occurred from September 2018 through December 2020, with follow-up through June 2021.

Intervention:

Participants were randomized to one of two dietary intervention groups. Data including height, weight, BP, blood samples and 24-hour dietary recalls were collected at baseline, 3 months and 6 months. Participants in both groups received the same written information on standard physical activity based on recommendations from the US Department of Health and Human Services. Group education sessions were moved to videoconference March 2020 during Covid. The intervention groups were as follows:

- **Low Carbohydrate Dietary Intervention Group:**
 Participants received behavioral counseling and supplemental food – **Phase 1 (Go Low):** 1st 3 months (target < 40 g net CHO/day). This phase involved weekly individual sessions for the first 4 weeks, followed by 4 small group sessions held every other week and 4 telephone follow-ups.
 – **Phase 2 (Keep it low):** Months 4 – 6 (target net carbohydrates < 60 g/day). This phase included 3 monthly group sessions and 3 telephone follow-ups
- **Usual Diet Group:** Participants received written information with standard dietary advice, but it was not ongoing. Monthly educational sessions unrelated to diet were optional.

Results:

- A total of 150 participants – 88 Black (52%), 37 White (49%), 7 Hispanic (9%) were randomized in the study; 142 of them (96%) completing the 6-month data collection.
- The mean HbA1c was 6.16%. Eighty seven percent of patients had untreated HbA1c less than 6.5%.
- The mean standard deviation (SD) body mass index (BMI) was 35.9 kg/m².

- Intakes of total and net carbohydrates, added sugars, and sugar-sweetened beverages were lower in the intervention group at follow-up, as was daily glycemic load; percentages of calories from protein and monounsaturated and polyunsaturated fats were higher at follow-up, though total intake for monounsaturated and polyunsaturated fats was higher only at 3 months.
- Compared with the usual diet group, the low-carbohydrate diet intervention group had significantly greater 6-month reductions in HbA1c, fasting plasma glucose, and body weight. Baseline, 3 month and 6-month results are noted in table 1.

Table 1: Change in Metabolic Risk Factors from Baseline, Within and Between Groups

Variable	Change from baseline – Low carb diet	Change from baseline – Usual diet	Difference in change from baseline – intervention vs. control	P-value
Hemoglobin A1c % – 3 mo	-0.23	-0.07	-0.16	<0.001
Hemoglobin A1c % – 6 mo	-0.26	-0.04	-0.23	<0.001
Fasting plasma glucose mg/dL, 3 mo.	-2.4	5.6	-8.0	0.007
Fasting plasma glucose, mg/dL, 6 mo.	-8.4	1.9	-10.3	0.001
Body weight, kg, 3 mo.	-4.6	-0.4	-4.1	<0.001
Body weight, kg, 6 mo.	-6.4	-0.5	-5.9	<0.001
Systolic BP mm Hg – 3 mo	-4.2	-0.2	-4.0	0.03
Systolic BP mm Hg – 6 mo	-4.9	-1.6	-3.2	0.12
Diastolic BP mm Hg – 3 mo	-3.2	-0.1	-3.2	0.01
Diastolic BP mm Hg – 6 mo	-3.2	-0.6	-2.6	0.05

Conclusions:

A low carbohydrate diet followed for 6 months in medication naïve adults with Type 2 diabetes with a baseline HbA1c between 6 and 6.9%, led to a clinically significant decrease in HbA1c, fasting glucose and weight loss. This approach supports the role of low carbohydrate diets in individuals with Type 2 diabetes and may have implications for individuals with prediabetes, specifically those seeking a plan to help decrease or maintain A1C levels in a range without medication use. If sustained, this meal planning approach also supports weight loss and improvement of other markers of metabolic syndrome, however more research is needed in this area.

Access the study:

<http://dx.doi.org/10.1001/jamanetworkopen.2022.38645>

References:

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