A Low-Carbohydrate Diabetes Prevention Program for Adults with Prediabetes: A Mixed Methods Pilot Study

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OBJECTIVES

1. To evaluate feasibility and acceptability of a Low-Carbohydrate Diabetes Prevention Program (LC-DPP) among adults w/ prediabetes
2. To estimate weight loss from a LC-DPP

BACKGROUND

The CDC’s National Diabetes Prevention Program (NDPP) is the prevailing public health strategy for type 2 diabetes prevention. However, recruitment of individuals into NDPP is challenging. The NDPP teaches a low-fat, calorie-restricted diet, and many NDPP participants do not achieve clinically-significant weight loss of ≥ 5% body weight.

Low-carbohydrate diets may be more effective for weight loss among individuals with prediabetes (carbohydrate-insulin hypothesis).

METHODS

Design: single-arm pilot study with mixed methods evaluation
Inclusion criteria: BMI ≥ 25 kg/m2 and prediabetes (HbA1c 5.7-6.4%)

Intervention:
• Adapted DPP dietary content to teach participants to follow a low-carb (<25 g net carbohydrate/day) rather than a low-fat/calorie-restricted diet
• 16 weekly sessions (core); 6 bi-monthly/monthly sessions (maintenance)
• Community partnership with National Kidney Foundation of Michigan

Quantitative Measures:
• Feasibility (rate of recruitment)
• Acceptability (session attendance)
• Change in weight
• Change in HbA1c

Qualitative Measures:
Semi-structured interviews at 6 months (n=13) and 12 months (n=12)

RESULTS

Recruitment

180 individuals invited (postal letter)
178% responded (n=32)
12% enrolled within 2 weeks (n=22)
22 participants

6- and 12-month outcomes

<table>
<thead>
<tr>
<th>Outcomes (mean (SD) or N(%))</th>
<th>6 months</th>
<th>12 months</th>
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</thead>
<tbody>
<tr>
<td>Core days attended</td>
<td>10.3 (4.5)</td>
<td>NA</td>
</tr>
<tr>
<td>Maintenance days attended</td>
<td>NA</td>
<td>3.4 (2.7)</td>
</tr>
<tr>
<td>Weight change (kg)</td>
<td>-4.3 (4.9)</td>
<td>-4.9 (5.8)</td>
</tr>
<tr>
<td>% weight change</td>
<td>-4.5 (5.0)</td>
<td>-5.9 (7.1)</td>
</tr>
<tr>
<td>≥ 5% weight loss</td>
<td>10 (45.5)</td>
<td>9 (42.8)</td>
</tr>
<tr>
<td>≥7% weight loss</td>
<td>6 (27.3)</td>
<td>8 (36.4)</td>
</tr>
<tr>
<td>≥10% weight loss</td>
<td>4 (18.2)</td>
<td>6 (27.3)</td>
</tr>
</tbody>
</table>

HbA1c change

n=18 at 6 months and n=19 at 12 months

Side Effects and Adverse Events

• No significant differences in side effects (e.g., constipation, diarrhea, headache)
• Ischemic stroke (n=1)

CONCLUSIONS AND NEXT STEPS

A Low-Carbohydrate Diabetes Prevention Program (LC-DPP) is feasible and acceptable.

Greater weight loss than historical controls in low-fat DPPs (5.9% v. 4.2%).

Uncertainty about dietary fat and disease risk is a challenge to implementation.

Comparative effectiveness trial of low-carb vs. low-fat DPP

Key Themes

Facilitators of adhering to a low-carb meal plan

Highly effective for weight loss
Decreased hunger and cravings

Barriers of adhering to a low-carb meal plan

It’s hard to give up carbs
Concerns about dietary fat

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Baseline characteristics (n=21)

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Value</th>
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<tbody>
<tr>
<td>Mean age in years (SD)</td>
<td>58.9 (11.0)</td>
</tr>
<tr>
<td>Female, n (%)</td>
<td>9 (42.9%)</td>
</tr>
<tr>
<td>White, n (%)</td>
<td>18 (85.7%)</td>
</tr>
<tr>
<td>Education &gt; HS, n (%)</td>
<td>17 (85.0%)</td>
</tr>
<tr>
<td>Married / partnered, n (%)</td>
<td>15 (71.4%)</td>
</tr>
</tbody>
</table>

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Decreased hunger and cravings
- "I like the fact that I’m not craving food and thinking about food all the time.
- Female, 8.63 kg (9.5% body weight) at 12 months

Barriers of adhering to a low-carb meal plan
- "It’s hard to give up carbs"
- "The hardest thing is avoiding food that I like or love, like breads and mashed potatoes and potato chips and pasta and going out to dinner and having a nice, big juicy hamburger on a nice bun."
- Male, -3.6 kg (3.6% body weight) at 12 months

Concerns about dietary fat
- "For years and years and years, I’ve heard eating red meats, cheeses, and nuts, and low carbohydrate foods...is not good for your coronary system, your heart. And now it seems like the whole thing is reversed. That’s the only thing that bothers me."
- Male, -2.2 kg (2.3% body weight) at 12 months

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