

A Mixed Methods Pilot Study of a Low-Carbohydrate Diabetes Prevention Program Among Adults with Prediabetes

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ABSTRACT

Objective: (1) To evaluate the feasibility and acceptability of a Low-Carbohydrate Diabetes Prevention Program (LC-DPP) among adults with prediabetes; (2) To estimate weight loss from a LC-DPP.

Methods: Single-arm mixed methods pilot study. We adapted the Center for Disease Control and Prevention's National Diabetes Prevention Program to teach participants to follow a very low-carbohydrate diet (VLCD). We recruited adults with body mass index ≥ 25 kg/m² and prediabetes from one primary care clinic. Primary outcome measures were feasibility (e.g., enrollment, retention as measured by rates of survey completion) and acceptability (e.g., session attendance, qualitative feedback). Secondary outcome measures were change in weight, achievement of $\geq 5\%$ weight loss, and change in hemoglobin A1c. During semi-structured interviews, we explored facilitators of and barriers to VLCD adherence.

Results: 22/187 individuals (12%) enrolled. One person dropped out before a baseline weight was obtained, and thus data from 21 individuals were analyzed. Fifteen individuals (71%) completed the 12-month survey. On average, participants attended 10.3/16 core sessions and 3.4/7 maintenance sessions. Mean (SD) weight loss was 4.3 (4.9) kg at 6 months and 4.9 (4.8) kg at 12 months. Among semi-structured interviewees (n=14), 3 factors facilitated adherence to a VLCD: (1) enjoyment of low-carbohydrate foods (2) diminished hunger and cravings; and (3) health benefits beyond weight loss. Three factors hindered adherence to a VLCD: (1) enjoyment of high-carbohydrate foods; (2) lack of social support; and (3) difficulty pre-planning meals.

Conclusions: A LC-DPP is feasible, acceptable, and may be effective for weight loss among adults with prediabetes.

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INTRODUCTION

An estimated 84 million U.S. adults have prediabetes, an asymptomatic state associated with an elevated risk of developing T2DM (1). Fortunately, individuals with prediabetes can prevent progression to T2DM. The landmark Diabetes Prevention Program (DPP) Trial demonstrated a 58 percent reduction in the 3-year incidence of T2DM among individuals with prediabetes who achieved at least 7 percent body weight loss through diet and physical activity changes (2). Accordingly, the Centers for Disease Control and Prevention (CDC) adapted the DPP's individual lifestyle intervention to a group-based program, which is now available in communities across the United States (3,4) and covered by a growing number of health plans, including Medicare (5).

Although the DPP is the prevailing public health strategy for T2DM, rates of program uptake and engagement are very low (6–8) and only 35% of real-world DPP participants achieve goal weight loss of at least 5% (4). A variety of efforts aim to augment DPP uptake and engagement, including public health campaigns to increase individuals' prediabetes risk awareness (9), initiatives to encourage primary care providers to identify and treat patients with prediabetes (10), and online and mobile health program adaptations to accommodate differences in individuals' needs and preferences (11). In contrast, no efforts, to our knowledge, specifically aim to increase the DPP's weight-loss effectiveness. Yet, doing so is critical, as weight loss is the key driver of T2DM risk reduction (12), and insurance payment hinges, in part, on participants' achievement and maintenance of at least 5% body weight loss (5).

One promising strategy to increase the DPP's weight loss effectiveness may be to change the program's dietary advice. The DPP was developed in the 1990s and thus teaches individuals to follow a low-fat, calorie-restricted diet, as this was the contemporaneous recommendation for healthy eating (15). However, the scientific merit of this recommendation has been criticized (15), and growing evidence supports the efficacy of low-carbohydrate diets (defined <26% total energy from carbohydrate per day) and VLCs (defined as <10% of total energy from carbohydrate per day)(16) for short-term weight loss

(17–19), long-term weight maintenance (20–22), and improved glycemic control, particularly among individuals with T2DM and insulin resistance (16,23,24).

Several prior studies have effectively used VLCDs to promote weight loss among patients with prediabetes (25,26). However, these interventions are costly and often require specialty care, which limit their ability to be scaled. In contrast, the NDPP uses non-medical coaches to deliver the program in a variety of community-based settings (27). Accordingly, we hypothesized that a low-carbohydrate Diabetes Prevention Program (LC-DPP) may be better for weight loss and T2DM prevention than the traditional, low-fat DPP, and, if effective, a LC-DPP could be readily scaled using lay educators and existing DPP infrastructure and systems for monitoring and ensuring program fidelity (28). This mixed methods pilot study has two aims: (1) to test the feasibility (e.g., enrollment and retention rates) and acceptability (e.g., session attendance, qualitative feedback) of a LC-DPP; and (2) to estimate weight loss from the intervention.

METHODS

We conducted a single-arm pilot study to test the acceptability, feasibility and preliminary efficacy on weight loss of a LC-DPP among individuals with prediabetes (clinical trial reg. no. NCT03258918, ClinicalTrials.gov). The study was approved by the University of Michigan Institutional Review Board and conducted from August 2017 to October 2018. We used a mixed methods intervention design with quantitative data collected at baseline, 6-months, and 12-months and semi-structured interviews conducted at 6-months and 12-months. The purpose of embedded qualitative interviews was to better understand participants' experiences with the intervention and to help explain our quantitative findings (29).

Setting and Participants

Individuals were recruited from one Michigan Medicine primary care clinic. Inclusion criteria were: (1) overweight, defined as body mass index (BMI) ≥ 25 kg/m² (30); (2) hemoglobin A1c (A1c) between 5.7-6.4% drawn within 6 months of the study start date; (3) willing to participate in group-based classes; and (4) able to engage in at least light physical activity. Exclusion criteria were: (1) history of

type 1 diabetes or type 2 diabetes; (2) current participation in another lifestyle or behavior change program or research study; (3) following a vegetarian or vegan dietary pattern (4) inability to read, write, or speak English; (5) inability to provide informed consent; or (6) pregnant or intention to become pregnant during the intervention period. We used an Electronic Health Record (EHR) reporting tool to identify individuals who met study eligibility criteria. A study invitation letter was sent to 187 individuals. Individuals interested in study participation emailed the study team and were then screened by telephone to ensure they met study eligibility criteria. Informed consent was obtained electronically using RedCap, a secure survey platform (31).

Intervention

The CDC offers two approved DPP curricula: (1) 2012 National Diabetes Prevention Program (NDPP) and (2) *Prevent T2* (cite). While *Prevent T2* is a newer program iteration, it has not been evaluated in peer-reviewed literature (4) and its effectiveness as compared to the 2012 NDPP is unknown. To facilitate comparison between our LC-DPP and published data on community-based DPPs, we modified the CDC's NDPP rather than *Prevent T2*.

The NDPP curriculum consists of 16-weekly sessions delivered over 6 months (i.e., core phase) followed by 6-8 bimonthly or monthly sessions (i.e., maintenance phase). In addition to teaching participants to follow a low-fat diet, the program also instructs individuals to engage in at least 150 minutes of moderate intensity physical activity per week and to use behavioral strategies (e.g., problem solving) to maintain lifestyle changes over time.

We adapted the NDPP's dietary advice to teach participants to follow a VLCD, restricting carbohydrate intake (not including fiber) to 20-35 grams per day during the program's core phase. Allowable foods included: meats, fish, poultry, eggs, cheese, seeds, nuts, leafy greens, non-starchy vegetables, and some fruits (e.g., berries). Participants were also taught to use low-carbohydrate substitutes when cooking or baking (e.g., almond flour in place of wheat flour). To minimize potential side effects (e.g. headache, constipation, muscle cramps, diarrhea, general weakness) participants were instructed to replace one meal a week with a low-carbohydrate alternative, starting with breakfast and

snacks. During the LC-DPP's maintenance phase, participants were instructed to gradually reintroduce carbohydrates (e.g., 5 non-fiber grams of carbohydrates per week) if: (1) they had met their weight loss target and (2) if they desired to liberalize their carbohydrate intake. Consistent with NDPP operating procedures, LC-DPP participants were asked to maintain daily food logs; these were submitted to the lifestyle coach at each session and then returned to participants with written feedback on food choices at the following session.

We partnered with the National Kidney Foundation of Michigan (NKFM), a local leader in community-based NDPP delivery. We trained an experienced NKFM lifestyle coach to deliver the LC-DPP. Training consisted of: (1) the coach's self-guided review of LC-DPP materials and online low-carbohydrate resources; (2) in-person training with the coach and study team, totaling approximately 4 hours; and (3) assessment of the coach's low-carbohydrate knowledge using a 22-item survey (**Appendix 1**). During the training period, our coach adapted her personal eating habits to adhere to a low-carbohydrate meal plan; she continued this eating pattern throughout the study period.

Participants' primary care physicians (PCPs) were notified via HIPAA-compliant messaging that their patient(s) was/were participating in this study. PCPs received written material about the study as well as potential side effects of low-carbohydrate diets and management strategies (e.g., magnesium for muscle cramps).

Primary Measures: Feasibility and Acceptability

Primary outcome measures were feasibility (e.g., uptake and retention rates) and acceptability (e.g., session attendance, qualitative feedback). LC-DPP uptake rate was defined as the number of participants recruited to the intervention divided by the total number of individuals invited to participate. LC-DPP retention rate was determined by calculating the rate of completion of the 6-month and 12-month surveys. Because some individuals remained engaged in the intervention (e.g., communicated via email with the coach) despite personal barriers to in-person session attendance, we used survey completion rate rather than a session attendance threshold (e.g., attendance at 9 core sessions) to measure study retention.

Intervention acceptability was determined by calculating the rate of attendance at core and maintenance sessions. Rates of session attendance were compared with the CDC's Diabetes Prevention Recognition Program (DPRP) standards (28). The DPRP monitors the fidelity and quality of community-based DPPs, and requires that at least 60% of program participants attend ≥ 9 core sessions and ≥ 3 core sessions. To further understand the program's acceptability, we conducted semi-structured interviews at 6 and 12 months. During interviews, we explored participants' general experiences with the intervention as well as specific facilitators of and barriers to VLCD adherence.

Secondary Measures:

Change in body weight: Body weight was measured and recorded at each attended session. We calculated average body weight change and percent body weight loss at the end of the program's core phase (6 months) and maintenance phase (12 months). Among session non-attendees, we attempted to schedule 6- and 12-month weigh-ins at participants' convenience within 2 weeks of the final core and maintenance sessions. All weights were obtained using the same calibrated scale.

Change in A1c: Baseline A1c was identified according to study inclusion criteria and abstracted from the electronic health record (EHR). Primary care physicians were notified that their patient(s) was/were participating in this intervention and they were asked to order A1c at 6 and 12 months. Change in A1c was calculated by subtracting participants' A1c at 6 and 12 months from baseline values.

Online Surveys: At baseline, 6 months, and 12 months, study participants were invited to complete an online survey via RedCap (31). At baseline, participants were asked to provide demographic and socioeconomic information. In each survey, we assessed participants' experiences of physical symptoms, which are known to be potential side effects of VLCDs. These include: bad breath, acne, gastrointestinal symptoms (e.g. constipation, diarrhea), dizziness, dry mouth, excessive thirst, headaches, and muscle cramps. Survey response options were: not at all; 1 day a week; 2-3 days a week; 4-5 days a week; and 6-7 days a week.

Analysis

Quantitative analysis

Descriptive statistics were used for baseline survey response data including demographic and socioeconomic characteristics and self-reported side effects. For all continuous outcomes, mean change and standard deviation from baseline to 6 months and 12 months were calculated. We used paired *t*-tests to compare self-reported physical symptoms at 6 and 12 months compared to baseline. All analyses were conducted using Stata 14.

Qualitative analysis:

Semi-structured interviews were recorded and transcribed verbatim. Interviews were imported into qualitative analysis software. Two investigators independently read and coded transcribed interviews. Interviews were then coded jointly using consensus conferences. Interviews were analyzed using directed content analysis, meaning the codes were created to reflect the main topics in the interview guide and to characterize the patterns and themes that emerged from the data (32).

Integrated analysis

Integration—the mixing of quantitative and qualitative data (33)—occurred after the study period. We merged qualitative data with weight loss data to better understand the factors that might have influenced weight loss outcomes.

RESULTS

Intervention uptake: A total of 187 potentially eligible individuals were sent study invitation letters via postal mail. Thirty-two individuals (17%) expressed interest in study participation and 22 (12%) enrolled in the study within two weeks. Reasons for non-enrollment included: unable to reach (n=4); active participation in another weight loss intervention (n=2); unwilling or unable to participant in group classes or follow VLCD (n=3). One person was placed on a waitlist because we met our recruitment target (n=22), which was determined by room-size constraints. One participant fractured her foot prior to the first session and could not be weighed due to casting and non-weight-bearing status. This participant

dropped out of the study after the third session due to worsening of chronic constipation and headaches, which she attributed to carbohydrate-restriction. She was excluded from our analyses due to absence of baseline weight data.

Baseline Characteristics

Demographic and socioeconomic characteristics were assessed at baseline (**Table 1**). Most participants were males (57%), white (86%), and educated, with 85% attaining education beyond high school. The mean age was 58.9 years (SD 11.0). At baseline, mean BMI was 34.1 kg/m² (SD 5.4) and mean A1c level was 5.9% (SD 0.22%).

Quantitative Analyses:

Retention: Eighteen out of 21 participants completed the 6-month survey and 15 completed the 12-month survey, resulting in a retention rates of 86% and 71%, respectively.

Session attendance: Participants attended a mean (SD) of 10.3 core sessions and 3.4 (2.7) maintenance sessions. Fourteen participants (67%) attended at least 9 core sessions and 11 participants (52%) attended at least 3 maintenance sessions.

Change in weight and A1c level: **Table 2** shows weight and A1c outcomes at 6 and 12 months among all participants (n=21) and among those who completed the 12-month survey (n=15). No participants progressed to T2DM, defined by A1c >6.4%, during the study period.

Change in self-reported physical symptoms: There were no statistically significant differences in self-reported side effects at 6 or 12 months compared to baseline.

Qualitative Analyses:

Participant Experiences with the Intervention

Fourteen participants participated in semi-structured interviews; 13 participated at 6-months and 12 participated at 12-months. During these interviews, we explored participants' experiences with the program, including barriers to and facilitators of adhering to a low-carbohydrate meal plan. At 12 months, we also explored participants' plans to continue to follow a low-carbohydrate meal-plan. These

qualitative data were integrated with interviewees' weight change data to better elucidate factors that may influence participants' weight change.

Over half (n=8, 57 percent) of interviewees were female. Other baseline characteristics were similar between interviewees and non-interviewees (**Table 1**). At 12 months, mean (SD) percent body weight loss among interviewees was 7.0 (6.5) percent. Half (n=7) of interviewees achieved the program goal of $\geq 5\%$ body weight loss at 12 months. **Table 3** shows key themes and representative quotes stratified by weight goal achievers and non-achievers.

Among weight goal achievers (n=7), three key themes emerged that facilitated adherence to the low-carbohydrate meal plan: (1) enjoyment of low-carbohydrate foods (2) diminished hunger and cravings (3) health benefits beyond weight loss.

The majority of weight goal achievers (n=5), found the meal plan to easy to follow due to palatability of the diet and availability of low-carbohydrate substitutes for foods such as potatoes and rice. One participant noted, "In the lunch time, I'll substitute [sandwich bread] with a low-carb wrap. There's a 4-gram wrap that I could use...The only thing you're replacing at dinner time from a carb standpoint would be maybe some potatoes or pastas, and [there are] really great substitutes...there's a low-carb pasta option. And then of course [there's] cauliflower mashed potato. When you are doing something like a taco salad with cheese and meat and sour cream and salsa, all of that fits [in the meal plan]."

Over half (n=4) of weight goal achievers noted diminished hunger and cravings. For example, one participant commented, "I just love that I'm losing weight. It's the best diet I have ever been on, and I've been on a lot. And it seems effortless, it just seems like it's melting off. And I'm eating good and I'm not hungry..." Another noted "when I eat a higher fat diet, I'm not hungry. And that's been a big surprise to me." One weight goal non-achiever endorsed diminished hunger when she adhered to the low-carb meal plan; however, she also described social pressures to consume carbohydrates and non-adherence to the intervention at least 1-2 days per week.

Almost all (n=6) weight goal achievers experienced health benefits in addition to weight loss, which motivated their continued adherence to the low-carbohydrate meal plan. Several participants

described increased energy levels and improved sleep. One stated, “[I was able] to decrease my blood pressure medications...[I’m] someone who's been on high blood pressure medication for probably 15, 20 years, now it's cut in half, so that's significant.”

Among weight goal non-achievers (n=7), three key themes emerged that hindered adherence to the low-carbohydrate meal plan: (1) difficulty giving up high-carbohydrate foods; (2) lack of social support; and (3) difficulty planning ahead.

The majority of weight goal non-achievers (n=5) described difficulty giving up carbohydrates due to food preferences, and this was a particular challenge in the absence of social support. One participant commented, “the hardest [part is that] it's so much fun to go out for ice cream with my friends or just to go to a restaurant. And I don't like to have to order a salad or something... It's just kinda hard I guess, being around other people who are eating stuff that I shouldn't have.” Another commented, “I live with somebody who eats things that I should not have. And it's become very difficult to resist those, especially as I go farther and farther into the program.” In contrast, only one weight goal achiever noted difficulty giving up carbohydrates. However, this challenge was mitigated by the support of a spouse who also adhered to the meal plan: “The hardest thing for me, personally, is that I love bread, and I love potato, [but] as long as [my spouse and I] are working together on this, we're great.”

Several weight goal non-achievers (n=3) described difficulty with planning low-carbohydrate meals. One noted, “probably the [biggest challenge] is the pre-planning that you have to do...[when] I was going grocery shopping, I had meals planned, and...I was doing much better than if I run out of food and I'm hungry and I just want something now.”

Almost half (n=6) interviewees expressed concern about potential adverse health consequences of increased dietary fat intake, including heart disease and elevated cholesterol levels. One participant stated, “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. You gotta understand the last 50 years, [All I heard] was...sausage and steak and hamburger, and pork chops are not good for you. They're

not good for your heart. But now it seems like things are changing. That's the only thing that bothers me. Otherwise, it's working great.”

DISCUSSION

We tested the feasibility and acceptability of a Diabetes Prevention Program in which participants were taught to follow a carbohydrate-restricted rather than a fat-restricted meal plan. Twelve percent (n=22) of eligible individuals enrolled in our study within 2 weeks of receiving an invitation letter. LC-DPP participation was slightly higher than that observed in traditional DPPs (6–8), including those offered by our institution’s self-funded health plan (34). Given room-size limitations and the pilot nature of this study, we ceased recruitment efforts once we met our enrollment target and we may therefore be underestimating potential LC-DPP participation. Over half of LC-DPP participants were male while the majority of NDPP participants are female (4). Study retention, as measured by survey completion, was high (85%, n=18) at 6 months and decreased at 12 months (70%, n=15). Similarly, attendance at LC-DPP core sessions was high, meeting CDC DPRP standards (28) with 67% (n=14) attending at least 9 core sessions; attendance decreased during the program’s maintenance phase with only 52% (n=11) attending at least 3 maintenance sessions.

To our knowledge, this is the first study that aims to augment the weight loss effectiveness of the CDC’s NDPP by modifying the program’s dietary advice. At 12 months, percent body weight loss among all LC-DPP participants was greater than weight loss among historical NDPP controls (5.2% versus 4.2%) and a greater number of LC-DPP participants achieved at least 5% body weight loss (46.7% versus 35.5%) (4). Meta-analyses of NDPPs demonstrate a positive association between session attendance and body weight loss (4,27). Due to sample size limitations, we were unable to evaluate the relationship between LC-DPP attendance and body weight change. However, among our sample, weight change was greater among survey completers (n=15) as compared to survey non-completers at 6 months (6.2% versus 4.5%) and 12 months (6.4% vs. 5.2%).

During qualitative interviews, we explored facilitators of and barriers to low-carbohydrate dietary adherence. These data not only provide insight into the factors that may influence individuals' weight change outcomes, but also reveal potential opportunities to refine and tailor the intervention. For example, consistent with prior literature (35), our participants identified social support as a key factor in dietary adherence, suggesting that LC-DPP partner classes and or peer-support programs may be one strategy to augment program adherence. Furthermore, interviewees that achieved goal weight loss described enjoyment of the low-carbohydrate diet as compared to weight goal non-achievers who struggled to give up the carbohydrate-rich foods that they loved. Participants that do not adhere to the low-carbohydrate meal plan due to non-enjoyment of allowable foods may benefit from other evidence-based interventions for T2DM prevention (e.g., traditional DPP, metformin) or weight loss (e.g., Weight Watchers, pharmacotherapy, bariatric surgery), and these alternatives should be readily offered.

The majority of interviewees expressed fear regarding the diet's fat content, reflecting the widely-held belief that dietary fat and cholesterol increase cardiovascular disease risk. While observational data demonstrating this association emerged in the 1950s (36), the causative role of dietary saturated fat and cholesterol in heart disease is not well-established (37). Furthermore, the Women's Health Initiative, the largest randomized controlled trial to evaluate health outcomes of low-fat diet adherence, showed no reduction in cardiovascular disease risk among intervention versus control group participants (38). Growing literature demonstrates favorable changes in cardiovascular disease risk factors (e.g., blood pressure) and serum biomarkers (e.g., LDL, HDL, and triglycerides) among individuals following low-carbohydrate, high-fat diets (16,17,19,22). Accordingly, the 2015-2020 U.S. Dietary Guidelines removed prior recommended limits on dietary fat and cholesterol intake, and clinical practice guidelines for T2DM (39) and obesity management (40) now endorse carbohydrate restriction as one evidence-based approach to lifestyle modification. Despite these changes, however, pervasive fears regarding dietary fat remain one primary barrier to implementation of a LC-DPP. We plan to revise the LC-DPP curriculum to better address participants' concerns and we will test serum lipids in future program evaluations.

LIMITATIONS

First, we recruited individuals from one primary care clinic within an academic medical center, and our results are not generalizable to other populations. Second, we did not evaluate outcomes beyond 12 months, and are therefore able to assess long-term adherence to a carbohydrate-restricted meal plan. Finally, because this was a pilot study designed to evaluate feasibility and acceptability, we cannot assess the intervention's weight loss effectiveness. A large-scale comparative effectiveness trial of the LC-DPP versus traditional DPP is warranted.

CONCLUSIONS

The CDC's NDPP is widely available throughout the United States. Yet, rates of program uptake and engagement are low and many program participants do not achieve the program's weight loss goal of at least 5%. A DPP adapted to teach participants to follow a low-carbohydrate rather than a low-fat diet may be one effective way to increase the program's weight loss effectiveness. In this study, we demonstrate that a LC-DPP is feasible and acceptable. Future work is needed to evaluate the LC-DPP's weight loss effectiveness as compared to the NDPP. It is critical to explore issues concerning dietary adherence and sustainability as well as biomarker (e.g., lipid, A1c) changes and incident chronic disease (e.g., T2DM, cardiovascular disease) over time. Lastly, future work should explore the factors that facilitate or hinder LC-DPP weight loss success (e.g., presence or absence of social support) and develop tailored strategies that address these factors.

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DUALITY OF INTEREST

Dr. Griauzde, Dr. Saslow, Kaitlyn Patterson, Tahoor Ansari, Brad Liestenfeltz, Aaron Tisack, Patti Bihn, Samuel Shopinski, and Dr. Richardson declare that they have no conflicts of interest.

AUTHOR CONTRIBUTIONS

D.G., L.S., and C.R. designed the study. D.G., L.S., K.P., and A.T. developed the intervention. K.P., T.A., B.L., P.B., and S.S. collected the data. D.G. and C.R. analyzed the data; they take full responsibility for the integrity of data analyses. D.G. drafted the manuscript. All authors critically revised the manuscript.

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TABLES

Table 1. Baseline characteristics

	All participants (n=21)	Program completers ¹ (n=15)	Semi-structured interviewees (n=14)
Mean age in years, mean (SD)	58.9 (11.0)	60.5 (10.2)	58.7 (9.4)
Male, n (%)	12 (57.1)	8 (53.3)	6 (42.9)
White, n (%)	18 (85.7)	13 (86.7)	12 (85.7)
Education > high school, n (%)	17 (85.0)	12 (80.0)	13 (92.9)
Married / partnered, n (%)	15 (71.4)	12 (80.0)	10 (71.4)
Mean BMI in kg/m ² , mean (SD)	34.1 (5.4)	33.9 (4.2)	32.7 (3.1)
Baseline A1c, mean (SD)	5.9 (0.2)	6.0 (0.2)	5.9 (0.2)

¹Defined as having completed the 12-month survey.

Table 2. 6-month and 12-month results among all participants (n=21) and 12-month survey completers (n=15).

Outcomes (mean (SD) or N(%))	6 months		12 months	
	All (n=21)	Completers (n=15)	All (n=21)	Completers ¹ (n=15)
Weight change in kg	-4.3 (4.8)	-6.0 (4.7)	-4.9 (5.8)	-6.1 (6.1)
Percent weight change	4.5 (5.0)	6.2 (4.8)	5.2 (6.0)	6.4 (6.4)
At least 5% weight loss	9 (42.9)	9 (60.0)	9 (42.8)	7 (46.7)
At least 10% weight loss	3 (14.2)	3 (20.0)	6 (27.3)	5 (33.3)
A1c change	-0.1 (0.2)	-0.2 (0.2)	0.06 (0.3)	0.04 (0.4)

¹Defined as having completed the 12-month survey.

Table 3. Key themes and representative quotes stratified by percent body weight loss.

Key Theme	Representative Quotes
≥5% body weight loss at 12 months (n=7)	
Enjoyment of low-carbohydrate foods	<p>“[I'm eating] all the cheese and the meat and the vegetables I'm allowed. I'm enjoying all of it. And I found snacks like sugarless jello...beef sticks, salami with cheese...and I'm really enjoying it...If I have cake it'll be here and there, like for a party, but I know that I can get right back on this diet in the next day.”</p> <p style="text-align: right;"><i>-14.5 kg (18% body weight) at 12 months</i></p>
Diminished hunger and cravings	<p>“I don't have cravings. I like the fact that I'm not craving food and thinking about food all the time.”</p> <p style="text-align: right;"><i>-8.6 kg (9.5% body weight) at 12 months</i></p>

Health benefits beyond weight loss	<p>“By losing the weight, I feel more active. It seems like my joints don’t hurt as bad.”</p> <p><i>-14.5 kg (14% body weight) at 12 months</i></p>
≤5% body weight loss at 12 months (n=6)	
Difficulty giving up high-carbohydrate foods	<p>“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. Just taking the bun off, not having pasta, not having mashed potatoes, I miss that. But, if I see the weight loss keep going, I’m okay to tolerate that.”</p> <p><i>-3.6 kg (3.4% body weight) at 12 months</i></p>
Lack of social support	<p>“It’s very hard sometimes when you’re traveling with friends, going on road trips, going to restaurants, watching everybody eat, the high carbohydrate food, being of a Mediterranean descent with pastas and stuff like that, spaghettis and pizzas and noodles, it’s very hard to adhere to it at times.”</p> <p><i>-2.2 kg (2.3% body weight) at 12 months</i></p>
Trouble pre-planning meals	<p>“I think just like with any sort of food awareness...there’s time involved, and it’s just hard to pre-plan and make meals that would benefit me and that my kids would like.”</p> <p><i>-0.63 kg (0.6% body weight) at 12 months</i></p>