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Mixed methods pilot study of a low-carbohydrate diabetes prevention programme among adults with pre-diabetes in the USA

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ABSTRACT

Objectives (1) To estimate weight change from a low-carbohydrate diabetes prevention programme (LC-DPP) and (2) to evaluate the feasibility and acceptability of an LC-DPP.

Research design Single-arm, mixed methods (ie, integration of quantitative and qualitative data) pilot study.

Setting Primary care clinic within a large academic medical centre in the USA.

Participants Adults with pre-diabetes and Body Mass Index of ≥25 kg/m^2.

Intervention We adapted the Centers for Disease Control and Prevention's National Diabetes Prevention Program (NDPP)—an evidence-based, low-fat dietary intervention—to teach participants to follow a very low-carbohydrate diet (VLCD). Participants attended 23 group-based classes over 1 year.

Outcome measures Primary outcome measures were (1) weight change and (2) percentage of participants who achieved ≥5% wt loss. Secondary outcome measures included intervention feasibility and acceptability (eg, attendance and qualitative interview feedback).

Results Our enrolment target was 22. One person dropped out before a baseline weight was obtained; data from 21 individuals were analysed. Mean weight loss in kilogram was 4.3 (SD 4.8) at 6 months and 4.9 (SD 5.8) at 12 months. Mean per cent body weight changes were 4.5 (SD 5.0) at 6 months and 5.2 (SD 6.0) at 12 months; 8/21 individuals (38%) achieved ≥5% wt loss at 12 months. Mean attendance was 10.3/16 weekly sessions and 3.4/7 biweekly or monthly sessions. Among interviewees (n=14), three factors facilitated VLCD adherence: (1) enjoyment of low-carbohydrate foods, (2) diminished hunger and cravings and (3) health benefits beyond weight loss. Three factors hindered VLCD adherence: (1) enjoyment of high-carbohydrate foods, (2) lack of social support and (3) difficulty preplanning meals.

Conclusions An LC-DPP is feasible, acceptable and may be an effective option to help individuals with pre-diabetes to lose weight. Data from this pilot will be used to plan a fully powered randomised controlled trial of weight loss among NDPP versus LC-DPP participants.

Trial registration number NCT03258918.

Strengths and limitations of this study

- This is the first study to explore a dietary strategy to augment the weight loss effectiveness of the Centers for Disease Control and Prevention's National Diabetes Prevention Program (NDPP).
- Mean weight loss among low-carbohydrate diabetes prevention programmmee (LC-DPP) participants was greater than mean weight loss among historical NDPP controls.
- An LC-DPP was feasible and acceptable among participants.
- This was a single-arm pilot study.
- Outcomes beyond 12 months were not examined.

INTRODUCTION

An estimated 84 million US adults have pre-diabetes and face an elevated risk of developing type 2 diabetes mellitus (T2DM).[1] Fortunately, individuals with pre-diabetes can prevent progression to T2DM. The landmark Diabetes Prevention Programme (DPP) Trial demonstrated a 58% reduction in the 3-year incidence of T2DM among individuals with pre-diabetes who achieved at least 7% 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 programme, which is now available in communities across the USA[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 programme 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 pre-diabetes,[10] and online and mobile health programme 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 programme'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.[13] However, the scientific merit of this recommendation has been criticised.[14] Growing evidence supports the efficacy of low-carbohydrate diets (defined as <26% total energy from carbohydrate per day) and very low-carbohydrate diets (VLCDs, defined as <10% of total energy from carbohydrate per day)[15] for short-term weight loss,[16–18] long-term weight maintenance[19–21] and improved glycemic control, particularly among individuals with T2DM and insulin resistance.[15 22 23]

Several prior studies have effectively used VLCDs to promote weight loss among patients with pre-diabetes.[24 25] Such interventions are often costly due to their use of individualised weight loss treatment and follow-up plans and subspecialty care, which limits their ability to be scaled. In contrast, the National Diabetes Prevention Program (NDPP) uses non-medical coaches to deliver the programme in a variety of community-based settings.[26] Accordingly, we hypothesised that a low-carbohydrate diabetes prevention programme (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 programme fidelity.[27] This mixed methods pilot study has two aims: (1) to estimate weight change from an LC-DPP and (2) to test the feasibility and acceptability of the intervention. These data will enable us to refine both the LC-DPP intervention and the methods and procedures (eg, recruitment and retention processes) in anticipation of conducting a fully powered randomised controlled trial (RCT) of weight loss among NDPP versus LC-DPP participants.

METHODS

We conducted a single-arm pilot study to estimate weight change from an LC-DPP and to examine the intervention's feasibility and acceptability among adults with pre-diabetes. We used a mixed methods sequential explanatory study design[28]; quantitative data were collected at baseline and at 6 and 12 months; qualitative data were collected at 6 and 12 months. Integration[29] of quantitative and qualitative data occurred after the study period when we merged our quantitative and qualitative data. The rationale for this approach is that quantitative data provide a general overview of the intervention's efficacy and limitations, and qualitative data help to explain these findings by exploring participants' experiences and perspectives in more depth.[30]

Setting and participants

Michigan Medicine has 14 adult primary care clinics throughout Southeast Michigan that serve approximately 240 000 patients with racial/ethnic characteristics similar to 2016 US Census Data estimates for the state of Michigan (80% white, 14% African–American, 5% Latino and 3% Asian).[31] Approximately 70% of Michigan Medicine patients have commercial insurance and approximately 30% have federal insurance (eg, Medicare and Medicaid). We conducted this study at one outpatient clinic with a demographic and payor mix similar to that of the health system.

Inclusion criteria were (1) overweight, defined as a Body Mass Index (BMI) of ≥25 kg/m^2 [32]; (2) haemoglobin A1c (HbA1c) between 5.7% and 6.4% drawn within 6 months of the study start date; (3) willingness to participate in group-based classes; and (4) ability 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 behaviour change programme 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.[33]

Intervention

The CDC offers two approved DPP curricula: 2012 NDPP and Prevent T2 (https://www.cdc.gov/diabetes/prevention/resources/curriculum.html). While Prevent T2 is a newer programme iteration, it has not been evaluated in peer-reviewed literature,[4] and its effectiveness as compared with 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 (ie, core phase) followed by 6–8 bimonthly or monthly sessions (ie, maintenance phase). In addition to teaching participants to follow a low-fat diet, the programme also instructs individuals to engage in at least 150 min of moderate intensity physical activity per week and to use behavioural strategies (eg, 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 fibre) to 20–35 g per day during the programme's core phase (ie, weeks 1–16). We did not substantially alter the content of NDPP sessions focused on non-dietary topics such as exercise. While the NDPP curriculum teaches participants to initiate adherence to a low-fat diet during session 2, we designed the curriculum to gradually ease individuals into the low-carbohydrate diet for two key reasons. First, we recognised that this dietary change may be drastic for individuals accustomed to consuming high-carbohydrate meals. Accordingly, we desired to increase individuals' competency and self-efficacy through step-by-step introduction of the meal plan, as these constructs have been associated with dietary adherence and favourable changes in health habits in other behaviour change studies.[34] Second, when transitioning to a very low-carbohydrate meal plan, individuals may experience side effects such as headache, constipation, muscle cramps, diarrhoea and general weakness (ie, 'keto influenza'); a more gradual reduction in carbohydrate intake can reduce the likelihood that individuals experience these symptoms. During session 2, participants were instructed to replace typical breakfast and snack foods with low-carbohydrate options. During sessions 3 and 4, they were instructed to replace lunch and dinner foods, respectively, with low-carbohydrate options. As part of these sessions, participants were also advised about strategies to mitigate potential side effects (eg, increase water and salt intake if experiencing headache, and increase intake of water and non-starchy vegetables if experiencing constipation). Allowable foods included meats, fish, poultry, eggs, cheese, seeds, nuts, leafy greens, non-starchy vegetables and some fruits (eg, berries). Participants were also taught to use low-carbohydrate substitutes when cooking or baking (eg, almond flour in place of wheat flour).

During the LC-DPP's maintenance phase, participants were instructed to gradually reintroduce carbohydrates (eg, 5 g of non-fibre carbohydrates per week if (1) they had met their weight loss target and (2) they desired to liberalise 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 (online supplementary file 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 Health Insurance Portability and Accountability Act (HIPPA)-compliant messaging that their patients 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 (eg, magnesium for muscle cramps).

Primary measures: weight change

1. Change in body weight at 6 and 12 months: Body weight was measured and recorded at each attended session. Among session non-attendees, we attempted to schedule 6 and 12 months of weigh-ins at the participants' convenience. We calculated average body weight change and per cent body weight change at 6 and 12 months compared with baseline. All weights were obtained using a calibrated scale.
2. Percentage of participants who achieved ≥5% body weight loss: At 6 and 12 months, we determined the percentage of participants who achieved goal weight loss by dividing the number of individuals who achieved ≥5% body weight loss by the number of study enrollees with baseline weight data (n=21). We similarly calculated the percentage of participants who achieved 10% body weight loss at each time point.

Secondary measures

Intervention feasibility and acceptability

Measures of feasibility and acceptability were uptake, session attendance and study retention rates. LC-DPP uptake rate was defined as the number of participants who enrolled in the intervention divided by the total number of individuals invited to participate.

Session attendance 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.[27] The DPRP monitors the fidelity and quality of community-based DPPs and requires that at least 60% of programme participants attend ≥9 core sessions and ≥3 maintenance sessions. We aimed to achieve these session attendance metrics to demonstrate LC-DPP feasibility.

LC-DPP retention rate was determined by calculating the rate of completion of the surveys at 6 and 12 months. Although session attendance is commonly used as a measure of intervention retention in larger trials, we observed that several participants in this small pilot study could not attend sessions due to personal and/or professional circumstances. However, they remained in periodic communication with the lifestyle coach, received course materials by e-mail, and completed assessments at 6 and 12 months. Accordingly, we felt that survey completion was the most accurate representation of study retention in this small sample.

To further understand the programme's acceptability, we conducted semistructured 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. The 6-month interview guide is shown in online supplementary appendix 2.

Change in HbA1c

Baseline HbA1c was identified according to study inclusion criteria and abstracted from the EHR. PCPs were notified that their patients were participating in this intervention and they were asked to order HbA1c at 6 and 12 months. Change in HbA1c was calculated by subtracting participants' HbA1c at 6 and 12 months from baseline values.

Online surveys

At baseline and 6 and 12 months, study participants were invited to complete an online survey via RedCap.[33] 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 (eg, constipation and diarrhoea), 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.

Exploratory analysis

We examined participants' weight changes stratified by 12-month survey completion (ie, study retention).

Sample size

Consistent with CONSORT guidelines[35] and other expert recommendations for designing pilot studies,[36–38] our sample size was selected based on pragmatic considerations with the goal of generating sufficient data to inform a fully powered RCT. Specifically, NKFM typically enrols 15–20 individuals in their programme, and the clinic's conference room has capacity for approximately 25 individuals. We specified an enrolment target to 22 individuals, as we believed this would maintain the group dynamic of NKFM's traditional DPPs while also allowing us to sufficiently test the feasibility of the methods and procedures (eg, recruitment and retention) that we are likely to use in a fully powered RCT.[35]

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, including body weight and HbA1c, we calculated mean change and SD from baseline to 6 and 12 months. Given our small sample and non-normal distribution of the data, we used a nonparametric statistical test, the Wilcoxon matched-pairs sign-rank test, to compare prechanges and postchanges in the frequencies of participants' self-reported physical symptoms at 6 and 12 months compared with baseline. All analyses were conducted using STATA V.14.

Qualitative analysis

Semistructured 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 analysed using directed content analysis, meaning the codes were created to reflect the main topics in the interview guide and to characterise the patterns and themes that emerged from the data.[39]

Integrated analysis

Integration—the mixing of quantitative and qualitative data[29]—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.

Patient and public involvement

There was no patient or public involvement in the development of this pilot study. Rather, we sought feedback from study participants. These results will be used to refine the intervention for a larger-scale trial, which will also be informed by stakeholder groups, including patients with pre-diabetes, primary care team members and community partners (eg, NKFM).

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 2 weeks. Reasons for non-enrolment included inability to reach (n=4); active participation in another weight loss intervention (n=2); unwillingness or inability to participate in group classes or to 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 dropped out of the study before a baseline weight could be obtained and was therefore excluded from our analyses.

Baseline characteristics

Demographic and socioeconomic characteristics were assessed at baseline (table 1). Most participants were men (57%), white (86%) and educated, with 85% attaining education beyond high school. The mean age was 58.9 years (SD 11.0). At baseline, the mean BMI was 34.1 kg/m^2 (SD 5.4) and the mean HbA1c level was 5.9% (SD 0.22%).

Quantitative analyses

Change in weight and HbA1c level

Table 2 shows weight and HbA1c outcomes at 6 and 12 months among all participants (n=21) and among those

Table 1 Baseline characteristics

	All participants (n=21)	Programme completers* (n=15)	Semistructured interviewees (n=14)
Mean age (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 (kg/m^2), mean (SD)	34.1 (5.4)	33.9 (4.2)	32.7 (3.1)
Baseline HbA1c, mean (SD)	5.9 (0.2)	6.0 (0.2)	5.9 (0.2)

*Defined has having completed the 12-month survey.
BMI, Body Mass Index; HbA1c, haemoglobin A1c.

who completed the 12-month survey (n=15). No participants progressed to T2DM, defined by an HbA1c level of >6.4%, during the study period.

Retention

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

Session attendance

Participants attended a mean of 10.3 core sessions and 3.4 (SD 2.7) maintenance sessions. Fourteen participants (67%) attended at least nine core sessions and 11 participants (52%) attended at least three maintenance sessions.

Change in self-reported physical symptoms

There was an increase in self-reported constipation from baseline to 6 months (p=0.006). There was a decrease in muscle cramps from baseline to 6 months (p=0.005) and a decrease in physical weakness from baseline to 6 months (p=0.05) and 12 months (p=0.05). There were no other statistically significant differences in self-reported side effects at 6 or 12 months compared with baseline.

Adverse event

One participant suffered an ischaemia stroke during the programme's core phase.

Qualitative analyses

Participant experiences with the intervention

Fourteen individuals participated in semistructured interviews; 13 participated at 6 months and 12 participated at 12 months. During these interviews, we explored participants' experiences with the programme, 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%) of interviewees were female. Other baseline characteristics were similar between interviewees and non-interviewees (table 1). At 12 months, mean per cent body weight loss among interviewees was 7.0% (SD 6.5). Half (n=7) of the interviewees achieved the programme goal of ≥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 and (3) health benefits beyond weight loss.

The majority of weight goal achievers (n=5) found the meal plan easy to follow due to palatability of the diet and

Table 2 Results at 6 and 12 months 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* (n=15)
Weight change (kg)	−4.3 (4.8)	−6.0 (4.7)	−4.9 (5.8)	−6.1 (6.1)
Per cent weight change	4.5 (5.0)	6.2 (4.8)	5.2 (6.0)	6.4 (6.4)
At least 5% wt loss	9 (42.9)	9 (60.0)	8 (38.1)	7 (46.7)
At least 10% wt loss	3 (14.2)	3 (20.0)	6 (27.3)	5 (33.3)
HbA1c change	−0.1 (0.2)	−0.2 (0.2)	0.06 (0.3)	0.04 (0.4)

*Defined has having completed the 12 month survey.

Table 3 Key themes and representative quotes stratified by per cent body weight loss

Key theme	Representative quotes
≥5% body weight loss at 12 months (n=7)	
Enjoyment of low-carbohydrate foods	'(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'. −14.5 kg (18% body weight) at 12 months
Diminished hunger and cravings	'I don't have cravings. I like the fact that I'm not craving food and thinking about food all the time'. −8.6 kg (9.5% body weight) at 12 months
Health benefits beyond weight loss	'By losing the weight, I feel more active. It seems like my joints don't hurt as bad'. −14.5 kg (14% body weight) at 12 months
≤5% body weight loss at 12 months (n=6)	
Difficulty giving up high-carbohydrate foods	'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'. −3.6 kg (3.4% body weight) at 12 months
Lack of social support	'It's very hard sometimes when you're travelling 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'. −2.2 kg (2.3% body weight) at 12 months
Trouble preplanning meals	'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'. −0.63 kg (0.6% body weight) at 12 months

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-carbohydrate 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) the 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

This is the first study, to our knowledge, that aimed to augment the weight loss effectiveness of the CDC's NDPP by modifying the programme's dietary advice. Specifically, participants were taught to follow a carbohydrate-restricted rather than a fat-restricted meal plan. At 12 months, the per cent body weight loss among all LC-DPP participants was greater than weight loss among historical NDPP controls (5.2% vs 4.2%) and a similar number of LC-DPP participants achieved at least 5% body weight loss (38% vs 35%).[4] Meta-analyses of NDPPs demonstrate a positive association between session attendance and body weight loss.[4 26] 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 with survey non-completers at 6 months (6.2% vs 4.5%) and 12 months (6.4% vs 5.2%).

Twelve per cent (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.[40] Given room-size limitations and the pilot nature of this study, we ceased recruitment efforts once we met our enrolment 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 were female.[4] Study retention, as measured by survey completion, was high (85%, n=18) at 6 months and decreased at 12 months (71%, n=15). Similarly, attendance at LC-DPP core sessions was high, meeting CDC DPRP standards,[27] with 67% (n=14) attending at least nine core sessions; attendance decreased during the programme's maintenance phase, with only 52% (n=11) attending at least three maintenance sessions. Notably, rates of attrition are often high in real-world behavioural health interventions, including traditional DPPs where approximately half of the participants remain engaged with the intervention at 6 months.[4 41] Accordingly, by CDC DPRP standards and in comparison to real-world DPPs, our findings suggest that an LC-DPP is feasible. Additional strategies (eg, incentives and varied class times) could be explored to augment participants' session attendance.

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,[42] our participants identified social support as a key factor in dietary adherence, suggesting that LC-DPP partner classes and/or peer-support programmes may be one strategy to augment programme adherence. Furthermore, interviewees who achieved goal weight loss described enjoyment of the low-carbohydrate diet as compared with weight goal non-achievers who struggled to give up the carbohydrate-rich foods that they loved. Participants who 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 (eg, traditional DPP and metformin) or for weight loss (eg, Weight Watchers, pharmacotherapy and 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,[43] the causative role of dietary saturated fat and cholesterol in heart disease is not well-established.[44] Furthermore, the Women's Health Initiative, the largest RCT to evaluate health outcomes of low-fat diet adherence, showed no reduction in cardiovascular disease risk among intervention versus control group participants.[45] Growing literature demonstrates favourable changes in cardiovascular disease risk factors (eg, blood pressure) and serum biomarkers (eg, low-density lipoprotein, high-density lipoprotein and triglycerides) among individuals following low-carbohydrate, high-fat diets.[15 16 18 21] Accordingly, the 2015–2020 US Dietary Guidelines removed prior recommended limits on dietary fat and cholesterol intake, and clinical practice guidelines for T2DM[46] and obesity management[47] now endorse carbohydrate restriction as one evidence-based approach to lifestyle management. Despite these changes, however, pervasive fears regarding dietary fat remain one primary barrier to the 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 programme evaluations.

LIMITATIONS

First, we recruited individuals from one primary care clinic within a US academic medical centre, and our results may not be generalisable to other populations. Because the prevalence of pre-diabetes is increasing worldwide,[48] there is a critical need to develop and test

novel interventions for T2DM prevention among diverse populations and concomitantly explore what works for whom and under what circumstances.[49 50] Second, we did not evaluate outcomes beyond 12 months and are therefore unable to assess long-term adherence to a carbohydrate-restricted meal plan. Finally, because this was a pilot study, we cannot assess the intervention's weight loss effectiveness compared with the NDPP. A large-scale comparative effectiveness trial of the LC-DPP versus NDPP is warranted.

CONCLUSIONS

The CDC's NDPP is widely available throughout the USA. Yet, many programme participants do not achieve the programme'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 way to increase the programme's weight loss effectiveness and to broaden the range of available programmes to help individuals with pre-diabetes. In future work, we aim to test the LC-DPP's weight loss effectiveness as compared with the NDPP in a RCT. It is critical to explore issues concerning dietary adherence and sustainability, as well as biomarker (eg, lipid and HbA1c) changes and incident chronic disease (eg, T2DM and cardiovascular disease) over time. Lastly, future work should explore the factors that facilitate or hinder LC-DPP weight loss success (eg, presence or absence of social support) and develop tailored strategies that address these factors.

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