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Measurement of Long-Term Diet Adherence Following a Randomized

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Introduction

Prostate cancer (PC) treatment alternatives are needed given that local therapies are not always curative and systemic therapies o entimes have unwanted side e ects. In PC xenogra s, both weight loss and low-carbohydrate diets (LCD) without weight loss prolong survival [1, 2]. Previously, our team conducted CAPS2, a 6-month randomized trial of ≤20g carbohydrates/day low carbohydrate diet (LCD) intervention vs. no dietary change in men with a rising prostate speci c antigen (PSA) a er failed surgery or radiation [3]. e LCD intervention was delivered weekly by a registered dietitian using telehealth strategies, primarily phone calls. e intervention was well-tolerated, resulted in signi cant weight loss (median of 12.3kg) and suggestively slowed tumor growth as measured by PSA doubling time. e purpose of this follow-up study was to determine if participants assigned to the LCD intervention in CAPS2, in comparison to the control participants, maintained the LCD and/or weight loss that occurred during the 6-month intervention period despite not being asked to continue the diet a er the 6-month study. We hypothesized that the bene ts of weight loss would encourage men from the LCD group to maintain some level of LCD relative to their pre-study diet.

Methods

Once follow-up measures were approved by each site's Institutional Review Board (IRB), all participants (n=45) who completed the original 6-month intervention between 2014 to 2018, regardless of randomization, were invited to participate in this follow-up study in 2020. Since CAPS2 was a multisite study, the participants from Cedars Sinai Medical Center (CSMC) were contacted and consented by a CSMC coordinator. Once informed written consent was obtained, the lead study dietitian called and conducted 24-hour food recall and collected self-reported weights from CSMC participants. For the Duke and Durham Veterans A airs sites, the lead study dietitian consented the participants and concurrently collected one 24-hour food recall

body mass index (BMI), and time to follow-up in months. e median time to follow-up were 37.1 and 37.3 months for the control and LCD groups, respectively. e median carbohydrate intake for the LCD group at follow up was slightly lower than that of the control group (145g vs 186g) though this was not signi cant (p=0.8). ere were no signi cant di erences in caloric, macronutrient intake, weight or BMI between groups at follow-up (all p≥0.2).

When diet adherence was examined as absolute (g) change from 6-month to follow-up, LCD participants signi cantly increased their carbohydrate intake a er the intervention (+118g; p=0.009 and +281%; p=0.002; Table 2). Although not signi cant, LCD participants' absolute carbohydrate intake remained slightly lower at follow-up than that at baseline (median -47g; p=0.6; Table 3). Notably, participants from the LCD group regained the majority of weight lost between the 6-month visit and the subsequent follow-up (median +15lbs; p=0.009; Table 2). Weight in the LCD group remained lower than that of the baseline measures, but this was not statistically signi cant (median -7 lbs; p=0.4; Table 2).

Discussion

e primary nding of CAPS2 suggested that LCD is not only safe for PC patients but also did not adversely a ect tumor growth. On the contrary, an LCD may slow PC progression and may bene t other metabolic risk factors [3]. Although no signi cant di erence was observed, our follow-up study showed a slight trend that the LCD participants consumed slightly less carbohydrates at follow-up than at baseline and their weights remained slightly lower than pre-study weights. However, overall, our follow-up suggests that diet adherence achieved during the 6-month intervention was not satisfactorily sustained and e ective strategies are needed to ensure long-term adherence.

Given the potential bene t of weight loss and LCDs on PC, long-term adherence strategies are warranted. A 2016 meta-analysis noted factors that a ect weight loss and dietary adherence, which include but are not limited to age, income, education, and social support systems [4]. e same analysis also reported that supervised attendance programs had greater adherence rates (68.6%), while self-monitoring programs had the lowest adherence rate (41.5%) [4]. Furthermore, a 2018 paper by Hall, et al. suggested several relevant strategies for promoting long-term weight loss maintenance including, but not limited to, post program weight loss speci c counseling, cognitive restructuring (referring to participant bingeing and negative thoughts), developing cognitive exibility (getting rid of the all or nothing attitude), and managing expectations [5]. For our CAPS2 population, no support was provided as it was designed to be a 6-month only study. We hypothesized that in a highly motivated cohort of patients with recurrence cancer, the weight loss bene ts alone would be su cient to maintain some level of diet adherence long-term. While there was

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randomization/balance may no longer hold. Furthermore, follow-ups were conducted at a di erent time frames for each participant. In terms of data collection, the study dietitian collected both diet and weight data from the participants which may present an opportunity of bias, though this bias should be comparable between groups. Additionally, participants' weights were self-reported which could be a source of error in the weight data.

A major strength of this analysis is that our team has conducted a rigorous RCT of LCD intervention and this follow-up extends those e orts. is follow-up shows how participants may tend to return to habitual intakes a er completing a strict 6-month dietary intervention without additional intervention to promote adherence; a common challenge among dietary intervention research.

Our nding suggests that while men randomized to a 6-month LCD may have made some slight long-term diet changes, the overall changes were modest and not signi cant. Among cancer survivors, it does not appear that dramatic weight loss is su cient of a motivator