Dietary Intake of Overweight and Obese Men Diagnosed with Prostate Cancer Before and After a Lifestyle Intervention

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Abstract

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Background: There is increasing evidence that obesity is correlated with prostate cancer (PC) progression and PC-related mortality among men on active surveillance (AS). Interventions aimed at weight loss among obese men on AS are not a current part of standard care. The Prostate Cancer Active Lifestyle Study (PALS) is an ongoing randomized control trail (RCT) where researchers are investigating the effects of a lifestyle intervention on biomarkers of glucose regulation and disease progression among overweight and obese men on AS. The PALS RCT provides an opportunity for researchers to examine dietary patterns of men before and after a lifestyle intervention. **Objectives:** The purpose of this study was to describe dietary intake of food groups targeted in the PALS intervention materials -fruits, vegetables, sweetened beverages, alcohol, added fats, sweets and desserts, and sweets as condiments- among PALS participants at baseline and to determine whether intake of these seven

categories significantly differed between and within two study arms, the intervention arm and control arm, from baseline to 6-months. **Hypothesis 1**: Among the intervention arm, average daily intake of fruit and vegetable servings would be significantly higher and average daily intakes of sweetened beverages, alcohol, added fats, sweets and desserts, and sweets as condiments would be significantly lower compared to the control arm. **Hypothesis 2:** At six-months, average daily intake of fruit and vegetables would be significantly higher and average daily intakes of sweetened beverages, alcohol, added fats, sweets and desserts, and sweets as condiments would be significantly lower among the intervention arm. **Methods:** PALS participants (n=23) were randomized to control or intervention. Participants in the control arm (n=11) were provided standard nutrition and exercise information through one, 30-minute session. Participants in the intervention arm (n=12) took part in a 6-month lifestyle intervention based on the Diabetes Prevention Program. Using 3-day food records collected at baseline and 6-months, dietary intake of the seven food categories was determined. Chi-squared and two-sample t-tests were used to assess demographic differences among participants at baseline. Two-sample t-tests were used to detect differences in intake between study arms and paired t-tests were used to detect differences within study arms. Two-samples t-tests were used to compare changes in mean intake between the study arms from baseline to follow-up. **Results:** There were no significant differences in intake at baseline nor at 6-months between the two study arms. There were no significant differences in intake between baseline and 6-months among controls. There was a borderline decrease in sweets and desserts from baseline to 6-months among participants in the intervention arm (1.17±1.38 servings/d to 0.43±0.68 servings/d, P=0.05). **Conclusions:** A lifestyle intervention may be a factor in the decreased intake of sweets and desserts among overweight and obese men on AS. Larger studies are needed to determine whether this intervention will illicit substantial changes in average daily intake of fruits, vegetables, sweetened beverages, alcohol, added fats, sweets and desserts, and sweets as condiments.

Background:

Prostate cancer (PC) is projected to be the most commonly diagnosed cancer in males in 2018.[1] Behind breast and lung cancer, it is the third most common cancer diagnosed in the United States (U.S.) It is estimated that there will be more than 160,000 new cases in 2018. With a mean age of diagnosis at 66 years of age, it is reported that 11.6 percent of men will be diagnosed with PC in their lifetime. PC is currently the sixth leading cause of cancer-related deaths in the United States, with a death rate of 20.1 deaths per 100,000 men.[2]

While common, PC can be slow growing; some men may never require treatment and doctors may recommend a less invasive approach such as active surveillance. Active surveillance (AS) is defined as a close monitored approach in which the individual is administered a prostate-specific antigen (PSA) blood test, as well as a digital rectal exam (DRE) once every six months. Prostate biopsies are conducted once per year. AS can be recommended when the individual is not experiencing symptoms, if the cancer is localized, and if it is expected to be a slow growing cancer based on the Gleason score.[3] A Gleason score is a grading system based on pathology of the prostate tumor tissue samples from biopsy. A lower score indicates a slow growing cancer that is less likely to metastasize.[4]

There are a number of lifestyle factors thought to be associated with PC-progression and PC-related mortality, including weight and dietary intake.[5-14] Based on NHANES 2009 and 2010 data, it is estimated that 74% of men are considered overweight or obese (body mass index [BMI], calculated as weight in kilograms over height in meters squared, greater than or equal to 25.0 kg/m^2.) Of these men, 36% are estimated to be obese (BMI greater than or equal to 30.0 kg/m^2) and 4% are estimated to be extremely obese (BMI greater than 40.0kg/m^2.)[15] Being overweight and obese may increase risk of a number of health complications.[16] Maintaining a

healthy weight aids in increasing overall health and may prevent PC development and progression.[17,18]

Several research studies have examined the relationship between BMI and PC.[5-7] Findings demonstrate that a higher BMI is associated with poor PC outcomes, including disease progression and death.[5-7] In a recent prospective study, Cantarutti et al. examined the association of BMI with PC-related mortality among 3,161 men diagnosed with PC, and found that PC-specific mortality was 44% higher in men with a BMI ≥27.5kg/m^2 compared to men with a BMI of 22.5 to 25.5 kg/m^2 (HR 1.44, 95% CI: 1.09-1.90).[6] In a long-term follow-up of the Physicians' Health Study, researchers assessed the relationship between BMI and PC-specific mortality.[7] Participants included men with PC seeking treatment and men on AS. After controlling for age at diagnosis, smoking status, PC clinical stage, and Gleason score, prostate-cancer specific mortality was 1.26 times higher in men who were overweight (HR 1.26, 95% CI 0.98-1.62) and 1.95 times higher in men who were obese (HR 1.95, 95% CI: 1.17-3.23.) There was a 1.07 increase in risk per unit increase in BMI (HR 1.07, 95% CI: 1.02-1.12.)[7]

The two previously mentioned studies included men undergoing various forms of treatment for PC, and very few studies have investigated the correlation between obesity and disease-related outcomes specifically in men on AS.[13] In a cohort of 565 men on AS, Bhindi et al. investigated the association of obesity and pathogenic and therapeutic progression of PC. Pathogenic progression was defined as no longer meeting low-risk criteria at follow-up and therapeutic progression was defined as the intent to begin therapy. Findings demonstrated that for every 5-point increase in BMI, risk of pathogenic progression increased by 50% (HR: 1.5;95% CI, 1.1-2.1; p=0.02) and therapeutic progression increased by 40% (HR: 1.4; 95% CI, 1.0-1.09; p=0.05).[13] In another observational study conducted on 230 men eligible for AS,

Ploussard et al. reported that men with a BMI >30 kg/m2 had a higher risk of disease upstaging(OR 4.2, 95% CI 1.7-10.6).[14]

It is also thought that certain dietary factors impact disease progression.[9,10,12] In an observational study of 1,560 men with non-metastatic PC, researchers reported an inverse association between total vegetable intake and risk of disease progression. While this association was not significant, researchers also reported that men with the highest intake of cruciferous vegetables had a 59% decreased risk of cancer progression when compared to men with the lowest intake (HR 0.41, 95% CI 0.22-0.76). This study included both men on AS and men who had sought treatment.[9]

Another observational study, conducted on 926 men participating in the Physician's Health Study diagnosed with non-metastatic PC, examined dietary intake and its effect on disease progression.[10] This study included men who had undergone PC-cancer treatment including radiation, hormone or chemotherapy, or surgery. Researchers identified two dietary patterns: a Prudent diet pattern and a Western diet pattern. The Prudent diet pattern consisted of high intakes of fruits, vegetables, fish, legumes, and whole grains. The Western diet pattern, consisted of higher intakes of red and processed meats, high fat animal products, refined grains, and processed snacks, sweets, and desserts. Men with the highest Western diet scores had a 2.5-fold increase risk of PC-specific mortality (HR 2.53, 95% CI: 1.00-6.42). Post-diagnostic Prudent pattern scores were associated with a decreased risk of disease-specific mortality. However, this association was not statistically significant.[10]

In an observational study conducted on 390 men who had previously undergone a prostatectomy, but no other form of cancer treatment, Strom et al. assessed the association between saturated fat intake and biochemical failure, defined as the rise in the blood level of

PSA after treatment. Findings demonstrated that men who consumed diets higher in saturated fat were more likely to develop biochemical failure when compared with men who consumed less saturated fat (HR 1.90, 95% CI: 1.16-3.11). Men who consumed more saturated fat were also more likely to experience shorter biochemical failure-free survival when compared to men who consumed lower intakes of saturated fat (26.6 vs. 44.7 months, p=0.004).[12]

The studies that have examined dietary intake and its association with disease progression and disease-related mortality were conducted on men with PC who had sought treatment for their disease as well as men on AS.[9,10,12] To the author's knowledge, there are no studies that have examined dietary intake and its association with disease outcomes using only men on AS. Further study is warranted as men on AS are a vulnerable population susceptible to disease-progression and death from PC. Moreover, studies that examine the effects of a lifestyle intervention on overweight and obese men on AS are limited.[19,20] Interventions that target modifiable lifestyle factors such as physical activity, changes in dietary habits, and weight may prove to be important interventions to implement while on AS.

The Diabetes Prevention Program (DPP) is a lifestyle-based intervention involving weight loss, increased physical activity, and dietary modifications and behavioral practices aimed to improve and sustain overall health.[21] While this intervention has proven successful in populations of men and women diagnosed with insulin resistance and type II diabetes[21], its use as an intervention for overweight and obese men diagnosed with PC has yet to be assessed.

The Prostate Cancer Active Lifestyle Study (PALS) is an ongoing randomized control trial conducted by researchers at the Fred Hutchinson Cancer Research Center. Through this study, researchers are investigating the effects of a 6-month lifestyle intervention based on the DPP on biomarkers of glucose regulation and pathologic features of prostate biopsy tissue

obtained as part of standard of care for active surveillance. A primary goal of PALS is to determine whether the DPP improves markers of glucose regulation and disease status. PALS researchers also want to determine whether participants within the intervention arm are able to sustain the encouraged lifestyle changes 6-months after the intervention period. All participants are provided nutrition and exercise advice at baseline; general verbal and written advice is given to participants within the control group at baseline, and participants within the intervention arm are provided an opportunity to attend one-on-one nutrition sessions with the PALS registered dietitian and up to 24 supervised exercise visits. PALS is actively enrolling participants; however, a number of participants have already completed the dietary intervention period.

To the author's knowledge, no studies have been conducted to evaluate changes in dietary intake among individuals on AS partaking in the DPP lifestyle intervention. The primary aim of this study was to describe average daily intake of seven food categories at baseline. These food categories are fruits, vegetables, sweetened beverages, alcohol, added fats, sweets and desserts, and sweets as condiments. The second aim was to determine whether the DPP lifestyle intervention led to significant changes in intake of any of these seven food categories between study arms at 6-months and within study arms from baseline to 6-months.

Thesis Hypothesis I:

Among men randomized to the PALS intervention arm, average daily intake of fruit and vegetable servings will be significantly higher and average daily intakes of sweetened beverages, alcohol, added fats, sweets and desserts, and sweets as condiments will be significantly lower compared to men randomized to the control arm after 6-months.

Thesis Hypothesis II:

Among participants within the intervention arm, average daily intakes of fruit and vegetables would be significantly higher and average daily intakes of sweetened beverages, alcohol, added fats, sweets and desserts, and sweets as condiments would be significantly lower at 6-months compared to intakes at baseline.

Methods

Study Population and Design

Data for this study were collected from participants enrolled in PALS. Eligible participants included men with histologically confirmed adenoma of the prostate who have elected AS; tumors must be clinically localized, with low or low-intermediate risk disease (T1C/T2a, Gleason Score less than or equal to 7 (3+4), PSA <20). Participants must also have had a measured BMI of 25kg/m^2 or greater and be physically able to take part in a diet and exercise program. Men who had recently (<1 year) or were already taking part in a commercial or structured weight loss program were ineligible. Other exclusion criteria included the use of androgen deprivation therapy (ADT) within the previous 12-months, significant cardiovascular disease that prevented participation in an exercise program; insulin dependent Diabetes Mellitus, and/or Metformin use, and current alcohol or narcotic abuse. Men with a medical doctor (MD) confirmed cognitive impairment were also excluded from this study.

Eligible men were recruited for PALS by clinical staff from urology clinics at the University of Washington (UW) Medical Center and the Veterans Affairs (VA) Seattle Puget Sound Healthcare System. Men outside the UW and VA attending community urology clinics were eligible to participate if they contacted PALS study staff directly and if study staff were granted access to their medical records. Recruitment efforts were targeted towards men living in the greater Seattle area. All procedures were

approved by the Institutional Review Boards of the participating institutions.

All study activities were conducted at the Prevention Center at Fred Hutchinson Cancer Research Center. At baseline, participants signed written informed consent and data were collected via standardized questionnaires regarding participants' age, family history of prostate cancer, race/ethnicity, smoking history, usual alcohol consumption, and usual physical activity. Weight and height were assessed in person by study staff using a standardized protocol. BMI was computed as weight(kg)/height(m^2). Usual dietary intake was collected via 3-day food records completed by all PALS participants at baseline and 6-months.

Dietary Assessment Tools

PALS participant 3-day food records collected at baseline and 6-months were used to assess average daily intake of seven selected food categories: fruits, vegetables, sweetened beverages, alcohol, added fats, sweets and desserts, and sweets as condiments. Food record and serving size booklets were provided by the Fred Hutch Nutrition Assessment Shared Resource (NASR). Participants received in-person instruction on food record completion. Participants were asked to record detailed descriptions and amounts of all foods and beverages consumed on two weekdays and one weekend day. The meal type (breakfast, lunch, dinner, and snack) and meal location (home or out) were also recorded.

Defining Food Categories

PALS intervention resources were reviewed to determine what food categories would be assessed in this study. The seven food categories were selected because they were mentioned as specific targets during the nutrition education sessions. Defining each food category was necessary in order to determine whether a food item matched the definition of any one food category. It was also important to define standard serving sizes for each category in order to quantify the number of servings consumed by

each participant. Definitions for each food category were obtained from the USDA MyPlate website[22], with the exception of alcohol, which was obtained from the National Institutes of Health, U.S. Department of Health and Human Services.[23] Definitions for each food category are provided in Table 1. Fruits were defined as fresh, frozen, or dried fruit; 100% fruit juice, and canned fruit. Tomatoes and cucumbers, botanically defined as fruit, were coded as a vegetable. One serving of fruit was defined as ½ cup. According to MyPlate, a ½ cup serving of fruit is equivalent to ½ cup fresh or canned fruit, ¼ cup dried fruit, and ½ cup of 100% fruit juice. Vegetables were defined as fresh, canned, frozen, or cooked vegetables, and 100% vegetable juice. One serving of vegetables was defined as ½ cup and was equivalent to 1 cup raw, leafy greens, ½ cup raw or cooked vegetables, and ½ cup of 100% vegetable juice. Sweetened beverages were considered any drink with added sweetener.[22] Sweetened beverages were coded as total ounces consumed, rather than a defined serving size. Alcohol was defined as any beverage containing alcohol including beer, wine, hard cider, or hard liquor. One serving of alcohol was considered 12 oz. beer, 5 oz. wine, or 1.5 oz. hard liquor.[23] Added fats were defined as any fat added to the meal, both at the table and while cooking. Avocados, olives, and coconut were coded as added fats. Though they have other nutritional attributes, most of the energy comes from fat and they are typically used to add a smooth or creamy texture to meals. Sweets and desserts were defined as any sweet or baked good. Sweets as condiments were defined as condiments that contain sugar or other sweetener used to sweeten or add a sweet or savory flavor to foods.[22] Fruit-based desserts with added sugar such as fruit pies, tarts, or crumbles were considered within the sweets and desserts category and not as a serving of fruit. A standard serving size for all foods within the categories of added fats, sweets and desserts, and sweets as condiments could not be defined as serving sizes of individual foods within these three categories differ substantially. Thus, serving sizes for added fats, sweets and desserts, and sweets as condiments were based on the serving size of individual foods provided in the United States

Department of Agriculture's National Nutrient Database for Standard Reference, Release 28. This database provides information on serving sizes and nutrient content for 8,789 different food items.[24]

Coding of Food Categories

Food records were entered into an Excel workbook in order to determine the amount of servings consumed by each PALS participant for all seven food categories. This method was selected over the use of a nutrient analysis system because the purpose of this study was to analyze average daily intake of servings of the seven identified food categories among PALS participants. Each 3-day food record was entered into a separate spreadsheet. Each food item reported by participants in their food record was entered into the spreadsheet as an individual item. Food items with multiple ingredients, such as a turkey and mayonnaise sandwich on whole wheat bread, were deconstructed and entered as individual ingredients. The quantities in household servings reported by participants were also entered. When exact quantities were not listed, a standard serving size was assigned based on the serving size provided in the USDA Database, Release 28.[24] Entering the individual foods and amounts reported by participants allowed the researcher to determine specifically how many numbers of servings of each individual food category participants were consuming.

Each food item entered into an individual food record was assessed to determine if it fit the definition of any of the seven food categories. When a participant listed consuming a food from one of the categories above, the amount reported was divided by the standard serving size for that category to assess the number of servings consumed. To prevent any overlap in categorization, mixed foods were deconstructed into individual ingredients or food groups using the same schema as described above. This assured that no one food item simultaneously fit into multiple food categories. When participants reported consuming a mixed dish, a recipe was used to ascertain the individual ingredients and amounts to include in the food record. To find an

appropriate recipe, the name of the mixed dish was entered into the Google search engine. A recipe that matched the mixed dish was then selected. The ingredients listed in the recipe were added to the participant's food record. The total amount of each ingredient was divided by the recipe serving yield to determine the portion of each ingredient. Foods that did not fit any of the seven defined categories were left uncoded. Some examples of such foods include grains such as hot or cold cereal or slices of bread, meat and fish such as a hamburger patty, a salmon fillet or slices of deli meat, and dairy products such as milk or yogurt.

Total intakes of each of the seven food categories were calculated by adding the total number of servings consumed over the three-day period. Average daily intakes were then determined by computing the average of the total intake for each food category. The data were verified through a quality control check; ten percent of all food records were blindly re-coded. Any discrepancies found were corrected and all data were reassessed to ensure every coding decision followed a uniform process.

Statistical Analysis

To assess dietary intake at baseline, average daily intake of each of the seven food categories was computed for all study participants together, and separately for intervention and control groups. A two-sample t-test was used to determine whether mean intake of the individual food categories differed significantly between intervention and control groups at baseline. To assess intakes at the six-month follow-up, average daily intake of the seven food categories was computed separately for intervention and control groups. A two sample t-test was used to determine whether average daily intake of the individual food categories differed significantly between intervention and control groups at 6-months.

Average daily intakes of the seven food categories for intervention group participants were computed at baseline and follow-up. For participants within the intervention group who completed food records at both baseline and follow-up (n=7), a paired t-test was computed to determine whether there was a significant difference in intake between the two time periods. Average daily intake of the seven food categories among control group participants were also computed at baseline and follow-up. A paired t-test was computed to determine whether there was a significant difference in intake among participants within the control group who completed food records at both baseline and follow-up (n=4).

Changes in mean intakes of each of the seven food categories were computed among participants in the intervention and control groups who completed food records at both baseline and follow-up. A two-sample t-test was used to compare the mean change in intake of each food category between intervention and control participants. A p-value of less than or equal to 0.05 was considered statistically significant. All analyses were conducted using Microsoft Excel software, version 15.26.

Results:

Baseline characteristics of the study population are shown in Table 2. Data from 23 participants were used for this study, which represents the number of participants with food record data available through February 28, 2018. A total of 12 participants were randomized to the control group and 11 participants randomized to the intervention group. Mean age of participants at baseline was 66.9 years. There were no significant differences in family history of prostate cancer, partnership status, race, BMI, and smoking status between intervention and control groups at baseline.

Dietary Intake at Baseline

Dietary records were obtained from participants at baseline (n=20), including participants randomized to the control group (n=8) and participants randomized to the intervention group (n=12). Average daily intakes of each of the seven food categories are provided in Table 3 for all participants, and separately by intervention and control. At baseline, participants consumed an average of 1.14 ± 0.90 servings of fruits and 3.04 ± 1.99 servings of vegetables per day. They consumed an average of 2.77 ± 4.50 ounces of sweetened beverages and 0.66 ± 1.04 servings of alcohol. Average baseline consumption of added fats were 3.01 ± 2.62 servings per day. Participants consumed an average of 0.78 ± 0.98 servings of sweets/desserts and 0.86 ± 1.55 servings of sweets as condiments.

Consumption of fruits, vegetables, sweetened beverages, sweets and desserts, and sweets as condiments were similar between participants in both arms at baseline; participants within the intervention arm tended to consume less alcohol and more added fats than participants within the control arm (0.32 ± 0.57 servings per day vs. 0.82 ± 1.07 servings per day and 3.71 ± 3.43 servings per day vs. 2.60 ± 1.42 servings per day, respectively.) Despite these findings, there were no significant differences in intake between the two groups at baseline.

Dietary Intake at Follow-Up

Intakes Among Intervention and Control Participants

Participant food records were collected at six-months (n=15), including records from participants randomized to the control group (n=8) and participants randomized to the intervention group (n=7). Average daily mean intakes for each of the seven food categories among both groups are shown in Table 4. At six-months, on average, participants within the control group tended to consume more alcohol, added fats, and sweets and desserts. Intakes were

0.43 ± 0.54 vs. 0.14 ± 0.38 servings per day of alcohol, 2.47 ± 1.58 vs. 1.49 ± 0.68 servings per day of added fats, and 0.93 ± 1.35 vs. 0.43 ±0.68 servings per day of sweets and desserts, among control and intervention participants respectively. These differences were not significantly different.

Intake Among Control Group Participants

Data from the four participants within the control group who completed food records at baseline and 6-months are given in Table 5. There was a slight decrease in the mean amount of alcohol and added fats consumed at six-months follow-up compared to baseline. Daily mean intake of alcohol decreased from 0.88 ± 1.35 servings per day to 0.48 ± 0.61 servings per day. The average servings of added fats consumed decreased from 2.92 ±0.65 servings per day to 2.38 ±1.03 servings per day. Despite these changes, there were no significant differences in intake among participants within the control group who completed food records at both baseline and follow-up.

Intake Among Intervention Group Participants

Data from the participants within the intervention group who completed food records at both baseline and 6-months (n=7) are provided in Table 6. There were noted declines in mean intakes of added fats, sweets and desserts, and sweets as condiments at six-months follow-up. Mean intakes of added fats decreased from 3.12 ± 2.02 servings per day to 1.49 ± 0.68 servings per day. The mean number of sweets and desserts consumed decreased from 1.17 ± 1.38 servings per day to 0.43 ± 0.68 servings per day. Mean intakes of sweets as condiments decreased from 1.25 ± 1.09 servings per day to 0.31±0.44 servings per day. However, only the difference in intake of sweets and desserts consumed at six-months follow-up was noted as slightly significant (p=0.05).

Changes in Intake Among Intervention and Control Groups

Intake of fruits and sweetened beverages remained similar among both groups. There was a noted decrease in vegetable intake among participants within the intervention group (-0.87 ± 1.84 servings per day). Intake of alcohol decreased among participants within the control group by -0.39 ± 0.79 servings per day. Consumption of added fats, sweets and desserts, and sweets as condiments decreased among participants within the intervention group; changes in intakes were noted as -1.64 ± 2.19, -0.75 ± 0.80, and -0.94 ± 1.17 servings per day, respectively. Consumption of added fats decreased among participants within the control group by 0.54 ± 0.71 servings per day; however, intakes of sweets and desserts and sweets as condiments remained relatively unchanged among control participants. Despite these changes, there were no significant differences in change in intake between the two groups.

Discussion:

The primary aim of this study was to describe intake of seven food categories among men on AS participating in a randomized control trial. Baseline intakes reveal that participants within this study tended to consume only about 1, 0.5 cup serving of fruit per day and 3, 0.5 cup servings of vegetables per day. They were also consuming approximately 3oz. of sweetened beverages per day and 0.66 of a serving of alcohol per day. Average intakes of added fats, sweets and desserts, and sweets as condiments were about 3 servings per day, 0.78 servings per day, and 0.86 servings per day, respectively.

Observing intake at baseline is beneficial as it provides insight on what overweight and obese individuals on AS were consuming prior to a lifestyle intervention. It is recommended that men, ages 51 years and over, consume 2 cups of fruits per day and 2.5 cups of vegetables per day. These data suggest PALS participants were consuming less than the recommended daily

servings of fruits and vegetables per day.[22] Moderate alcohol consumption among men ages 21 years and older is considered two servings of alcohol per day.[23] Participants from this study were consuming less than one serving of alcohol per day at baseline; this is considered a modest intake.

There are several observational studies that have examined dietary intakes of men with PC.[8-10,12,19,25] However, these studies often report intake of foods in terms of grams or quartiles, rather than by serving size.[8-10,12,19,25] Furthermore, many observational studies that have looked at dietary patterns in men with PC report on intakes of nutrients rather than food categories; their findings include intakes of total energy, total fat, saturated fat, and energy from carbohydrates.[8,19,25] Because intakes in this study were measured by serving size rather than percent of total calories, it is difficult to determine whether men were consuming more than the recommended amounts of added fats and added sugars. Therefore, it is hard to compare baseline intakes of PALS participants to other men with PC. There are studies that have examined intake of other food groups, such as dairy, by serving size.[10] However, to the author's knowledge, intake by serving size of the food categories addressed within this study have not been assessed among men on AS.

The second aim was to determine whether the DPP lifestyle intervention led to significant differences in intake. There were noted declines in consumption of added fats, sweets and desserts, and sweets as condiments among participants enrolled in the intervention group after a 6-month lifestyle intervention. While only the decline in consumption of sweets and desserts among participants within the intervention group was noted as borderline significant (1.17±1.38 servings to 0.43±0.68 servings, P=0.05), more significant declines may be observed in a larger sample size of participants.

Intakes of fruits, vegetables, and sweetened beverages remained similar between the two study arms and within the two study arms from baseline to follow-up. There was a noted decline in vegetable intake among participants within the intervention group when we analyzed mean change in intake (-0.87 ±1.84 servings per day). However, this decline was heavily influenced by one participant whose intake decreased by 3.4 servings of per day.

To the author's knowledge, only one other study has examined intake of food categories among men on AS partaking in a lifestyle intervention. The Men's Eating and Living (MEAL) Pilot Study, is a study conducted by Parsons et al. In this study, researchers analyzed the effect of a counseling-based lifestyle intervention on dietary habits in participants on AS.[20] Participants within the intervention group (n=29) were given structured nutrition advice through telephone-based counseling; participants were encouraged to consume seven servings of vegetables per day, including two servings of cruciferous vegetables, two servings of tomato products, and three servings of other vegetables. They were also instructed to consume two servings of whole grains and one serving of beans and legumes per day. Participants within the control group (n=13) were provided written materials with standard nutrition guidelines recommending five servings of fruits and vegetables per day.[20]

Dietary intake was assessed using a series of three, 24-hour dietary recalls at baseline and 6-months. Recalls were collected through a telephone interview and dietary intakes were analyzed using the Minnesota Nutrition Data System software. In their findings, researchers noted consumption of vegetables increased by 71% amongst participants within the intervention arm; intakes of cruciferous vegetables, tomato products, and other vegetables increased by 180%, 265%, and 48% respectively ($p<0.05$). Researchers also noted a significant increase in vegetable intake among participants within the intervention arm compared to participants within

the control arm after 6 months (71% vs. 26%, $p<0.05$).[20]

Our findings differ from those reported by Parsons et al; there was no significant increase in vegetable serving consumption among PALS participants. However, the MEAL study intervention was tailored specifically towards increasing intakes of vegetables. In contrast, the DPP used in PALS, was tailored towards decreasing overall calories and added fats. While DPP also encouraged consumption of vegetables, the PALS intervention did include specific dietary goals regarding vegetable consumption. Moreover, MEAL study investigators used 24-hour recalls rather than food records to assess intake and it was unclear how the authors defined serving sizes for each of the categories they assessed.[20]

Study Limitations

There are several limitations to this study that warrant consideration. This study consisted of a small(n=23) population of men recently diagnosed with low-risk PC. There is a greater potential for error in use of a small sample size as results are heavily influenced by one or few participants. Moreover, PALS participants only include men from the greater Seattle area. Dietary patterns vary by region, and dietary intakes among PALS participants at both baseline and follow-up are not generalizable to the overall population of men on AS. Furthermore, this study only examined intake of seven specific food categories; other food categories and nutrients were not addressed. Thus, it cannot be determined whether the PALS dietary intervention led to significant dietary changes outside of the food categories examined.

Dietary intake was based upon participant self-reported food records. While the use of 3-day food records has been demonstrated to be more accurate than validated food frequency questionnaires and 24-hour recalls, they too are subject to participant misreporting error.[26,27] When participants did not specify the exact amount of a specific food or dish they consumed,

standard portion sizes obtained from USDA database were used.[24] These portion sizes may not match the actual portion size consumed by the participant. When a participant reported consuming a mixed dish, a recipe was used to determine the ingredients and amounts consumed for that mixed dish. These recipes may not match actual ingredients or yield consumed by the participant.

Conclusion

Findings from this study suggest that a lifestyle intervention based on the DPP fosters modest changes in intakes of some of the foods and food groups targeted in the intervention including added fat, sweets and desserts, and sweets as condiments among overweight and obese men diagnosed with PC. While only the decrease in sweets and desserts was considered borderline significant in this study, further studies using data from a larger sample of men are needed in order to determine whether this intervention leads to greater changes in intake.

Table 1. The Food Categories, Definitions, and Serving Sizes Selected to Describe Dietary Intake of PALS Participants

Category	Definition
Fruit	½ cup serving equals • 1 small fresh fruit (2.5" diameter) • 1⁄2 cup canned fruit • 4 oz. 100% fruit juice • 1⁄4 cup unsweetened dried fruit
Vegetable	½ cup serving equals • 1 cup leafy vegetables, raw or cooked • ½ cup raw vegetables or cooked vegetables • ½ cup vegetable juice
Sweetened Beverage	• Any drink with added sugar or other sweetener with kcals
Alcohol	• 12 ounces of beer • 5 ounces of wine • 1.5 ounces of hard liquor
Added Fats*	Added fats are defined as any fat added to the meal before, during, or after cooking. • High Fat Condiments: butter, cream, animal fat such as lard, tallow, or suet; coconut oil, hydrogenated or partially hydrogenated oils, palm oil or palm kernel oil, shortening, stick margarine, mayonnaise and full-fat salad dressings • High Fat Toppings: nuts, olives, avocado
Sweets/Desserts*	All sweet, baked goods including, but not limited to pastries, cookies, pies, cakes, and doughnuts; candies, chocolate, ice cream, frozen yogurt, and custard.
Sweets as Condiments*	Condiments that contain sugar or sweetener used to sweeten or add a sweet savory flavor to foods (i.e. jams, syrups, honey, ketchup, barbeque sauce, sugar as a condiment, etc.)

*Serving sizes based on serving size of individual food, obtained from the USDA database.

Table 2. Baseline Characteristics of Participants in the Prostate Cancer Active Lifestyle Study

Number of Participants:	**All Participants (n=23)**	**Lifestyle Intervention Group (n=12)**	**Control Group (n=11)**	**p-Value[a,b]**
Age in years at baseline:				
Mean (±Standard Deviation)	66.9 (±6.1)	67.6 (±5.7)	66.1 (±6.7)	0.58[a]
Family history of prostate cancer:				
Men w/family Hx of PC	8	4	4	
Men w/o family Hx of PC	15	8	7	0.88[b]
Marital Status:				
Married or living as married	17	10	7	
Single	6	2	4	0.28[b]
Race:				
Caucasian	19	10	9	
Other	4	2	2	0.92[b]
BMI: (kg/m^2)				
25-29.9	9	5	4	0.79 [b]
≧30	14	7	7	
Mean BMI (kg/m^2)	31.77	30.69	32.94	0.32[a]
Current Smoker (%)	13%	8.33%	18.1%	0.48[b]
History of Smoking ≧100 cigarettes/cigars/pipes in lifetime	52.2%	50%	54.5%	0.83[b]

[a] Two-sample t-test testing difference in values between intervention and control participants at baseline

[b] Chi-Squared test testing differences in proportions between intervention and control participants at baseline

Table 3. Mean daily intakes at baseline of early stage prostate cancer patients enrolled in the Prostate Active Lifestyle Study[a]

Food Category	All Participants (n=20) Mean ± SD	Lifestyle Intervention Group (n= 12) Mean ± SD	Control Group (n=8) Mean ± SD	p-Value[b]
Fruits (servings per day)	1.14 (± 0.90)	1.14 (± 0.87)	1.30 (± 1.03)	0.71
Vegetables (servings per day)	3.04 (± 1.99)	3.33 (± 2.10)	2.93 (± 2.24)	0.69
Sweetened Beverages (ounces per day)	2.77 (± 4.50)	2.19 (± 5.04)	3.15 (± 3.90)	0.66
Alcohol (servings per day)	0.66 (± 1.04)	0.32 (± 0.57)	0.82 (± 1.07)	0.37
Added Fats (servings per day)	3.01 (± 2.62)	3.71 (± 3.43)	2.60 (± 1.42)	0.40
Sweets/Desserts (servings per day)	0.78 (± 0.98)	0.75 (± 1.17)	0.74 (± 0.90)	0.97
Sweets as Condiments (servings per day)	0.86 (± 1.55)	0.73 (± 1.03)	0.5 (± 0.91)	0.62

[a] Mean intake represents a 3-day average consumption over the course of three non-consecutive days.

[b] Two sample t-test testing the difference in mean intakes of intervention and control groups at baseline

Table 4. Mean daily intake of participants in the lifestyle intervention group and control group after a 6 mo. in the Prostate Active Lifestyle Study[a]

Food Category	Lifestyle Intervention Group (n=7) Mean ± SD	Control (n=8) Mean ± SD	p-Value[b]
Fruits (servings per day)	1.50 (±0.84)	1.24 (± 1.82)	0.74
Vegetables (servings per day)	2.41 (±1.25)	2.79 (±1.74)	0.64
Sweetened Beverages (ounces per day)	2.62 (±4.25)	2.33 (±4.82)	0.91
Alcohol (servings per day)	0.14 (±0.38)	0.43 (±0.54)	0.26
Added Fats (servings per day)	1.49 (±0.68)	2.47 (±1.58)	0.15
Sweets/Desserts (servings per day)	0.43 (±0.68)	0.93 (±1.35)	0.39
Sweets as Condiments (servings per day)	0.31 (±0.44)	0.33 (±0.54)	0.92

[a] Mean intake represents a 3-day average consumption over the course of three non-consecutive days.

[b] Two-sample t-test testing the difference in mean intakes of intervention and control groups at 6 months

Table 5. Mean intake in participants randomized to the control group at baseline and follow-up using paired data in the Prostate Active Lifestyle Study[a]

Food Category	Baseline (n=4) Mean ± SD	Follow-Up (n=4) Mean ± SD	p-Value[b]
Fruits (servings per day)	1.49 (±1.19)	1.88 (±2.43)	0.78
Vegetables (servings per day)	3.54 (±3.08)	3.63 (±1.87)	0.92
Sweetened Beverages (ounces per day)	1.33 (±2.67)	3.33 (±6.67)	0.65
Alcohol (servings per day)	0.88 (±1.35)	0.48 (±0.61)	0.39
Added Fats (servings per day)	2.92 (±0.65)	2.38 (±1.03)	0.23
Sweets/Desserts (servings per day)	0.64 (±0.94)	0.77 (±1.54)	0.73
Sweets as Condiments (servings per day)	0.08 (±0.17)	0.29 (±0.34)	0.43

[a] Mean intake represents a 3-day average consumption over the course of three non-consecutive days.
[b] Paired t-test testing the difference in mean intakes of control group participants at baseline and 6 months.

Table 6. Mean intake in participants randomized to the lifestyle intervention group from baseline to follow-up using paired data in the Prostate Active Lifestyle Study[a]

Food Category	Baseline (n=7) Mean ± SD	Follow-Up (n=7) Mean ± SD	p-Value[b]
Fruits (servings per day)	1.19 (±0.99)	1.50 (±0.84)	0.95
Vegetables (servings per day)	2.58 (±1.04)	2.41 (±1.25)	0.82
Sweetened Beverages (ounces per day)	1.33 (±2.55)	2.62 (±4.25)	0.57
Alcohol (servings per day)	0.41 (±0.66)	0.14 (±0.38)	0.13
Added Fats (servings per day)	3.12 (±2.02)	1.49 (±0.68)	0.10
Sweets/Desserts (servings per day)	1.17 (±1.38)	0.43 (±0.68)	0.05
Sweets as Condiments (servings per day)	1.25 (±1.09)	0.31 (±0.44)	0.08

[a] Mean intake represents a 3-day average consumption over the course of three non-consecutive days.

[b] Paired t-test testing the difference in mean intakes of intervention group participants at baseline and 6 months.

Table 7. Changes in mean intake in participants from baseline to follow-up by study arm[a]

Food Category	**Intervention (n=7)** Mean ± SD	**Control (n=4)** Mean ± SD	**p-Value**[b]
Fruits (servings per day)	0.30 ± 0.90	0.39 ± 2.58	0.94
Vegetables (servings per day)	-0.87 ± 1.84	0.09 ± 1.73	0.82
Sweetened Beverages (ounces per day)	1.29 ± 5.67	2.00 ± 7.96	0.87
Alcohol (servings per day)	0.27 ± 0.40	-0.39 ± 0.79	0.73
Added Fats (servings per day)	-1.64 ± 2.19	-0.54 ± 0.71	0.36
Sweets/Desserts (servings per day)	-0.75 ± 0.80	0.13 ± 0.67	0.10
Sweets as Condiments (servings per day)	-0.94 ± 1.17	0.21 ± 0.46	0.10

[a] Mean intake represents a 3-day average consumption over the course of three non-consecutive days.
[b] Two-sample t-test testing the difference in change in mean intakes of intervention and control groups

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