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A dietary intervention to elicit rapid and complex dietary changes for studies investigating the effects of diet on tissues collected during invasive surgical procedures

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INTRODUCTION

Findings from observational epidemiology studies on diet and chronic disease have been the primary source of evidence motivating large clinical prevention trials; however, the disappointing and sometimes unexpected findings from many of these trials suggest that it is critical to better understand the biological effects of dietary manipulations in target tissues before undertaking such large scale clinical trials. (1–4) Recently, the feasibility of using prostate tissues collected at diagnosis and surgery to study the effects of dietary manipulation on gene expression was demonstrated. (5) Designing a dietary intervention to support this research presented many challenges: the time between diagnosis and surgical treatment was short; the dietary intervention, which combined substantial reductions in both dietary fat and glycemic load, required complicated food choices; and eligibility was

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restricted to the limited population of men with newly-diagnosed prostate cancer who both elected surgical treatment and were willing to participate in a dietary intervention study during the 4 weeks preceding surgery. Therefore, the intervention needed to effect complex dietary change quickly, and it had to be feasible to deliver with minimal participant burden in order to yield high participation rates.

Well-established intervention approaches that could effect complex dietary change, such as education-based behavior change programs and direct participant feeding, were not suitable for our application. Behavior change programs, which focus on nutrition education, behavior modification counseling and social support, could not be delivered quickly enough to test the effects of dietary change over the four week study period. Feeding studies, which typically require participants to either live in or travel daily to a study center, were not feasible because eligible participants were drawn from a large catchment area and few would agree to travel daily to a study center. An alternative dietary intervention model was clearly needed.

This report describes a dietary intervention program designed to elicit rapid and complex dietary change during the 4-week period preceding prostate surgery, and gives results of a pilot study to evaluate the program's efficacy. In addition, this report describes the unique design elements that were critical to the success of this intervention and discusses the study settings in which this general intervention approach would be useful.

DIETARY INTERVENTION DESIGN AND DELIVERY

This dietary intervention program was developed for a pilot study that evaluated the feasibility of studying the effects of dietary change on gene expression in normal prostate epithelium. (5) The goal of the dietary intervention was to elicit rapid adoption of a low-fat and low-glycemic load diet or a comparison "standard American" diet, and maintain the diet during the 4-week period preceding prostate surgery. The low-fat/low-glycemic diet was defined as a total fat intake of 45 grams (based on a 2,000 kcal diet and 20% of total energy from fat) and total glycemic load of 100. The standard American diet was defined as a dietary fat intake of 80 grams (based on a 2,000 kcal diet and 35% of total energy from fat) and a total glycemic load of 200. Neither energy intake nor weight loss was addressed in either intervention.

The intervention design was based on the Consumer Information Processing Theory, in which a central tenet is that individuals will seek ways to simplify decision making. (6) The intervention purposefully excluded both nutrition education and behavior modification counseling and instead focused on menu planning. Participants selected a nutritionist-designed sample menu for each meal, and modified components of the menu to allow for individual food preferences. The intervention delivery was modeled after the Women's Healthy Eating and Living (WHEL) study (7). The intervention began with a single in-person counseling session to introduce the materials and was followed by regular telephone counseling to encourage their use. The intervention program is described in detail below.

Participants first met with a research nutritionist and were given a 24-page manual consisting of a brief description of the study diet, a set of sample menus, a food substitution guide called the "Red-light/Green-light" list, and menu planners. The sample menus included 15 breakfasts, 17 lunches, 17 dinners and 10 snacks, each designed to have a specific amount of fat and glycemic load. The low-glycemic/low-fat breakfast and lunch menus had less than 10 grams of fat and a glycemic load less than 30; dinner menus had less than 25 grams of fat and a glycemic load less than 40. Snack menus provided less than 5 grams of fat and a glycemic load less than 10. The standard American breakfast and lunch menus had at least 15 grams of fat and a glycemic load of at least 60; dinner menus had at least 50 grams of fat and a glycemic load of at least 70. The “Red-light/Green-light” food lists were based on fat and glycemic index values (8) and served as a reference guide allowing participants to personalize the sample menus according to their food preferences. The “Green-light” list included foods appropriate to eat as part of the study diet, while the “Red-light” list included foods to avoid. Similar to an exchange list, foods on the “Green-light” list could be substituted for comparable food items on the sample menus. Participants used the menu planner worksheets to record their planned meals as well as their substitutions to the sample menus.

During the initial in-person intervention session, the nutritionist reviewed the study manual with the participant and provided intensive counseling focused on individualized meal planning. Participants were asked to select preferred sample menus and, with the help of the research nutritionist, used the “Red Light/Green Light” lists to make substitutions to accommodate their food preferences and lifestyle. The participant recorded the resulting individualized menus on the menu planner, which served as a meal plan and guide for food shopping, preparation and portion sizes.

Following the in-person session, a research nutritionist used telephone contacts (every other day during the first week of the study, and one to two times per week thereafter) to provide additional guidance in using the study materials and motivate their use. During these calls the research nutritionist also conducted an informal dietary recall to assess the participant’s compliance with the study diet.

DIETARY INTERVENTION PILOT STUDY

Between September 2003 and November 2004, eight participants with newly diagnosed prostate cancer who elected radical prostatectomy as initial treatment were recruited from the Veterans Administration Puget Sound Health Care System. Participants were aged 45 to 75 years, with a body mass index (BMI) between 20 and 35 kg/m^2 and no evidence of metastatic disease or co-morbid conditions that would preclude dietary change. All men had organ-confined prostate cancer (pT2a/b) except one patient who had node-positive disease (pT2aN1). The research nutritionist contacted participants to schedule the initial intervention session, and all study activities were initiated within two weeks of diagnosis to allow sufficient exposure to the intervention diet before prostatectomy. Institutional review boards at the Fred Hutchinson Cancer Research Center and the Veterans Administration Puget Sound Health Care System approved all study procedures, and all participants signed written consent prior to randomization.

The initial in-person session with the research nutritionist lasted between one and two hours. During this session, participants were randomly assigned to one of two diet groups, either the low-fat/low-glycemic load or standard American (comparison) diet arm, after which the nutritionist initiated the appropriate dietary intervention. The intervention was delivered as described above, and was terminated on the day of the participant’s prostatectomy.

Each week, participants completed one unannounced 24-hour recall. Certified interviewers, who were blinded to study arm, collected dietary data which were analyzed using the Nutrition Data System software and database (version 37, University of Minnesota, Minneapolis, MN). Weight was measured at the time of randomization and prostatectomy. Mean intake of nutrients was calculated using the average of all post-randomization dietary recalls. Statistical tests for differences in nutrient intake between intervention and control arms were based on mixed models. The effect of the dietary intervention on weight change was calculated using a multiple regression model, in which the dependent variable was change in weight from baseline to time of prostatectomy and independent variables were baseline weight and a dummy variable for treatment arm. Statistical significance for all models was set at the two-sided P= 0.05 level. All statistical analyses were conducted using SAS (Version 9.1, SAS Institute, Inc., Cary, NC).

The average length of the intervention and the frequency of participant contact were similar for both diet arms (approximately 31 days and 1.5 calls per week). The duration of calls was shorter for the standard American arm, and gradually decreased in both arms over time. At baseline, participants in both arms were similar in age (61 versus 65 years, respectively), weight (91.4 kg versus 90.9 kg) and body mass index (29.1 versus 29.5).

Table 1 gives mean nutrient intake for each diet arm throughout the intervention. Compared to men in the standard American arm (n=4), men in the low-fat/low-glycemic arm (n=4) had a 49.4% lower glycemic load (p<0.001) and consumed 45.5% less fat (p=0.06). Differences between study arms in dietary fat intake and glycemic load were significant the first week and were sustained throughout the study (data not shown). Men in the low-fat/low-glycemic arm also consumed significantly less carbohydrate (p<0.01), sugar (p=0.05) and total energy (p<0.005), and more fiber (p=0.02) than men in the standard American diet arm. Participants in both diet arms reported intakes that met or exceeded the Dietary Reference Intakes for all nutrients except calcium, and vitamins D, E and K (data not shown). Table 2 gives the mean pre- and post-intervention weight, by study arm. Men on the low-fat/low-glycemic arm lost a mean of 5.3 kg compared to a gain of 0.8 kg in the standard American arm (p=0.04); the baseline-adjusted intervention effect was −6.1 kg (95% CI:−10.5,−1.6; p=0.02).

We examined the 24-hour dietary recalls to determine if specific dietary patterns contributed to the observed differences in nutrient intake. The difference in glycemic load between the diet arms was primarily attributable to differences in consumption of beverages. Sweetened beverages, including coffee drinks, sodas and juices, and alcoholic beverages contributed an average of 427 kcal per day to the dietary intake in the standard American arm and only 42 kcal per day to the low-fat/low-glycemic load arm. In contrast, the difference in fat intake between diet arms, which accounted for a difference in energy intake of almost 400 kcal per day, was spread over multiple food groups including added fats, meats, and dairy products.

DISCUSSION

Results of this small pilot study, although preliminary, do suggest that a relatively simple and minimally burdensome dietary intervention, consisting of only a single in-person counseling session, a set of sample menus and telephone follow-up, can elicit rapid and complex dietary changes that are maintained over a four-week study period. The sample menus and “Red-light/Green-light” food substitution lists guided all food choices, including food type and serving size, and thus this intervention program did not require nutrition education or behavior modification components. Men could make quick decisions about what to eat without investing time in learning about food and nutrition and without developing behavior change skills. In addition, by using telephone contacts instead of individual or group intervention sessions to deliver the intervention, eligible men who would otherwise not participate due to their distance from the study center could be successfully recruited. Furthermore, frequent telephone contacts allowed the study nutritionist to monitor and motivate compliance, thereby eliminating the need for multiple in-person contacts.

There are several notable differences between the dietary intervention model described here and the many other successful dietary intervention programs described in the published literature. Most importantly, this intervention program was designed to elicit rapid and short-term dietary change, in contrast to the focus of most other dietary interventions on achieving more gradual but long-term dietary change. One consequence of this focus on short-term change was that the duration of the intervention did not allow use of nutrition education and behavioral modification components. These are clearly important to the success of long-term dietary interventions, but results of this pilot suggest that they may not be necessary to successfully effect short-term change. This program also differs from the published models for short-term (less than 16 weeks) dietary change interventions. Of the short-term interventions that have also used minimally burdensome intervention designs, the dietary goals have involved relatively simple behavior changes, such as increasing the number of servings of fruits and vegetables (9–12). None of these addressed a dietary pattern as complex as a low-fat/low-glycemic diet. There are several published short-term interventions that have targeted complex dietary changes; however, these programs are difficult to deliver and burdensome for participants, requiring extensive nutrition education, multiple, in-person dietary counseling sessions with a research nutritionist (13–21) or extensive self-monitoring (e.g., recording fat or intakes of specific foods daily) (13–15, 17–20). Given these difficulties, it is not surprising that many short-term interventions that have targeted complex dietary changes simply provided foods to participants. (22–27)

There are several important limitations to this pilot study. The study was very small and evaluated a unique population of men recently diagnosed with cancer. Generalizability will require evaluations in larger and more diverse populations. There was no assessment of baseline diet and thus, despite randomization, there may have been differences in diet between the two study arms at baseline. The large differences in post-randomization self-reported diet between study arms suggest that men were compliant with the dietary goals; however, it is well known that self-reported diet can be biased by an intervention (28, 29). Nevertheless, the significant effect of the intervention on body weight is good evidence that the self-reported dietary changes attributable to the intervention did occur. Although not targeted by the intervention, weight loss is a consistently-observed effect of low-fat diet interventions (30, 31) and thus weight loss can serve as an objective proxy measure of dietary change.

CONCLUSION

Intervention studies in persons diagnosed with cancer who will receive surgical treatment offer a unique opportunity to study the mechanistic effects of diet in target tissues, and a new intervention program was developed for these studies. In a very small pilot study, this intervention elicited rapid, substantial and complex dietary changes during the short time period between diagnosis and treatment. This novel program may fill a gap in the existing dietary intervention modalities; it requires no nutrition education or behavioral change skills; it is minimally burdensome; it is feasible to deliver when a limited number of eligible study participants are geographically dispersed; and it can be delivered at relatively low cost.

If proven effective in larger studies, there is much potential for this intervention approach. The general design of this intervention could be applied to other types of studies in which participants are recruited from a limited sample population and hypotheses address the short-term effects of dietary modification. For example, studies collecting difficult-to-obtain tissues from persons undergoing surgical treatment or invasive diagnostic procedures, such as colonoscopy, breast biopsy or even liposuction, could use this intervention program to study effects of dietary change on these tissues. Research nutritionists could also modify the dietary intervention goals by developing new sets of sample menus and appropriate “Red-Light/Green-Light” food lists. Further research to evaluate, modify and further test this intervention approach is well motivated.

All materials used for this intervention are available from the authors upon request.

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Table 1

Nutrient intake during dietary intervention, by treatment arm

	Low-Fat/Low Glycemic Load n=4	Standard American n=4	
	Mean [b] ± sd [c]	**Mean [b] ± sd [c]**	**p-value [d]**
Glycemic load[a]	134.8 ± 6.0	266.3 ± 36.8	**<0.01**
Fat (grams)	51.0 ± 36.0	93.5 ± 8.4	0.06
Energy from fat (%)	28.6 ± 12.6	34.8 ± 3.7	0.38
Carbohydrates (grams)	178.0 ± 11.8	308.9 ± 46.5	**<0.01**
Energy from carbohydrate (%)	50.6 ± 10.4	51.8 ± 5.0	0.85
Protein (grams)	81.6 ± 10.9	82.9 ± 13.3	0.79
Energy from protein (%)	22.9 ± 3.0	14.2 ± 3.2	**<0.01**
Total dietary fiber (grams)	21.4 ± 4.0	12.6 ± 3.6	**0.02**
Total dietary sugars (grams)	73.3 ± 20.8	160.4 ± 68.1	**0.05**
Energy (kilocalories)	1466 ± 367	2394 ± 215	**<0.01**

[a]Glycemic load represents the overall glycemic effect of the diet based on an individual's total carbohydrate intake.

[b]Unadjusted means for dietary data represent the mean of the average dietary intake from multiple dietary recalls

[c]sd = standard deviation

[d]p-values for dietary data are from mixed models

Table 2

Mean weight (kilograms) before and after dietary intervention[a]

	Pre-Intervention	Post-Intervention	p-value
Low-Fat/Low-Glycemic (mean ± sd [b])	91.4 ± 20.1	86.1 ± 18.6	**<0.01**
Standard American (mean ± sd [b])	90.9 ± 12.8	91.7 ± 8.5	0.741
Intervention Effect (mean ± se [c])	**−6.1 ± 1.7**		**0.02**

[a] Adjusted for baseline weight

[b] sd = standard deviation

[c] se = standard error