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### CAM: Naturopathic dietary interventions for patients with Type 2 diabetes

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#### ABSTRACT

*Objective*: To test feasibility, acceptability, and preliminary effectiveness of a naturopathic dietary intervention in patients with Type 2 diabetes.

*Methods:* Prospective observational pilot study evaluating the change in clinical and patient-centered outcome measures following a 12-week individualized and group dietary education program delivered in naturopathic primary care.

Results: HbA1c improved in all participants (n=12); mean - 0.4% +/- 0.49% SD, (p=0.02). Adherence to healthful eating increased from 3.5 d/wk to 5.3 d/wk (p=0.05). Specific nutritional behavior modification included: days/week consuming  $\geq 5$  servings of fruit/vegetables (p=0.01), attention to fat intake (p=0.05), and -11.3% carbohydrate reduction. Measures of physical activity, self-efficacy and self-management also improved significantly.

*Conclusion:* A naturopathic dietary approach to diabetes appears to be feasible to implement among Type 2 diabetes patients. The intervention may also improve self-management, glycemic control, and have influences in other domains of self-care behaviors. Clinical trials evaluating naturopathic approaches to Type 2 diabetes are warranted.

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#### 1. Background

Clinical risk factor control is poor in patients with Type 2 diabetes (T2DM) in the United States. According to 1999–2004 National Health and Nutrition Examination Survey (NHANES) data, only 52.2% of adults with T2DM met the American Diabetes Association (ADA) goal for HbA1c control (<7.0%). Increasingly complex pharmaceutical strategies are contributing minimally; only 32% of patients on triple oral therapy (TZD, sulfonylurea, and metformin) have an HbA1c less than 7%. The prevalence of risk factors for diabetic complications, such as hypertension, obesity, and physical inactivity are also high. In 2007 67.0% of U.S. adults with diabetes reported having hypertension, 83.5% were overweight or obese, and 38.2% reported being physically inactive.

It is well established that adoption of a healthy lifestyle, especially good nutrition, is the cornerstone of diabetes treatment yet it is not frequently delivered and can be challenging for patients to understand and stay motivated.<sup>3,4</sup> Delivery of healthy lifestyle advice by primary care providers is low, even for diabetes. A 2002 study of primary care found nutrition counseling addressed in 45%

of visits for diabetes,with the duration of counseling averaging just 55 seconds (<20~s to >6~min). Data from the 2000 National Ambulatory Medical Care Survey revealed that among patients with diabetes, diet counseling was provided in 37% and physical activity counseling in 20% of visits.  $^6$ 

Complementary and alternative medicine (CAM) may offer novel approaches to addressing lifestyle behavior change for prevention and control of chronic diseases such as diabetes. Naturopathic medicine is of greatest interest as it is a whole-system of CAM most closely resembling conventional primary care in scope of practice, but with greater delivery of healthy lifestyle counseling. According to observational studies, healthy lifestyle interventions are routine in naturopathic clinical care for T2DM, with diet, physical activity, and stress management counseling incorporated into the majority of clinical encounters (80–100%). Use of CAM has been associated with engaging in positive health behaviors and self-care, however these findings may only apply to uniquely motivated patients. In Thus rigorous evaluations of the effectiveness of naturopathically delivered healthy lifestyle interventions are needed in more generalized patient populations.

The objective of this study was therefore to examine the feasibility and effectiveness of a naturopathic dietary intervention on clinical and patient-centered outcome measures in patients with T2DM.

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#### 2. Methods

Approval for the study was obtained from the University of Washington Human Subjects Division, Bastyr University Institutional Review Board (IRB), and Swedish Medical Center IRB in Seattle, WA. The study consisted of a pre-post evaluation of patient-reported outcomes and biomarkers of glycemic control and cardiovascular risk before and following a 12 week structured program in naturopathic nutrition for T2DM (described below).

Participants were recruited from registries of diabetes patients at academic medical clinics, flyers at diabetes education centers and clinics, and using online classified ads. Interested people were screened by phone and if eligible, scheduled for a medical screening. Of those still eligible, participants were informed of the program components and evaluation plan and gave consent prior to being enrolled.

Inclusion criteria consisted of: diagnosis of T2DM, HbA1c>7.5%, currently under the supervision of a primary care provider, and if taking oral medications, stable and titrated for 1 month. Participants could not be actively participating in a weight loss program and had to be willing to try an intensive dietary intervention for T2DM. If the participant was not the cook in the household, their spouse or significant other had to be willing to try the naturopathic nutrition program as well. Exclusion criteria were insulin use, untreated or controlled psychiatric illness, and serious co-morbid conditions including late-stage chronic renal disease, cancer, hepatitis, stage III/IV congestive heart failure or HIV/AIDS.

#### 2.1. Intervention

Table 1 summarizes the key elements of the naturopathic approach to dietary management. The program included a total of 10 h of active intervention over twelve weeks chosen intentionally to match the "dose" of nutrition and dietician services covered by Medicare. Ten hours also approximates time and attention recommendations by the American Diabetes Association. An expert panel of naturopathic diabetes experts were consulted to develop principles of treatment that matched their clinical experiences and

was subsequently presented at the national scientific meeting of naturopathic physicians to obtain feedback. From these themes, a protocol directing content for each session was developed following the methods of the Diabetes Prevention Program.<sup>12</sup> This is presented in Table 2.

The nutrition program was delivered as a combination of oneon-one naturopathic physician-delivered dietary counseling and bi-weekly group educational sessions conducted following potluckstyle dinners. Thirty minute physician visits took place during week 1, 3, 5, and 9 and included history, vitals, and physical exam, if appropriate, as well as nutrition counseling. Diet diary and selfmonitored glucose records were reviewed and discussed in the context of patient education and self-management (not analyzed as study outcomes). Individual caloric goals were set based on Harris-Benedict formulas for metabolism and activity level.<sup>13</sup> Nutritional counseling sought to address 1) achieving macronutrient balance, 2) specific functional food servings, and 3) identifying particular behavioral changes appropriate to the participant and household.<sup>14</sup> Motivational interviewing and cooperative problem solving were the primary strategies used. 15,16 A written plan along with educational materials as appropriate were given to participants at the end of visits.

The program also included group educational sessions and potluck meals. Group sessions occurred weeks 2, 4, 6, and 8 in the evening and lasted approximately 1½-2 h to include unstructured time for eating and socializing. Family members were encouraged to attend and participate. The educational modules included topics such as basic nutrition, how to read food labels and grocery shop. how to select healthier food when dining out, what happens in the body with T2DM, how to problem-solve around dietary habits, why organic and wild foods are significant, and how to understand and address eating behaviors such as emotional eating. Written handouts were provided in the form of a Cooking & Eating Manual. Pot luck style dinners encouraged peer accountability, participantgenerated recipe ideas, modeled health-promoting eating styles and portion control, and built support amongst participants. This type of group training has been shown effective in numerous lifestyle intervention trials. 17,18

**Table 1**Core components of naturopathic nutrition.

Dietary principle	Specific recommendation	Rationale
Macro-nutrient balance	20–40% CHO, 25–45% protein,	This is a lower carbohydrate
	15-35% fat	diet that is still diverse, well-balanced,
		and practically achievable
Low glycemic index	Select low GI carbohydrates by paying	Low GI foods have a reduced
	attention to fiber and whole foods	post-prandial glycemic spike and
		subsequently keep insulin lower
Micro-nutrient density	Select foods that provide maximal	Because diabetic diets are often low
	micro-nutrient intake per calorie	calorie, it is important to maximize
		nutrition, especially dietary
		antioxidant intake
Functional Foods	Based on individual needs, select foods	Functional foods are foods that have
	that have function beyond calorie or nutrients	physiologic effects attributable
		to constituents other than
		macronutrient content; i.e. oat
		bran to lower LDL
Understand quality of foods	Learn to select healthy fats. Make conscious	Some fats, like omega 3 fatty acids,
	choices about organic, wild, local foods	have beneficial effects on glycemic
		control, whereas trans fatty acids
		and saturated fat increase CV risk
Understand personal	Understand emotional and situational eating	Several eating patterns have been
eating behavior	habits to avoid overeating	linked to overeating; empowerment
		over negative habits creates change
		and lead to self-efficacy across diabetes
	Hadanka d Cada a saidh a asaa	self-care skills.
Cultivate healthful attitudes toward food	Understand food nourishes more	For example, children who eat meals
	than the physical body	with family at the table have lower
		rates of obesity.

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