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Evaluation of a naturopathic nutrition program for 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% +/- .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 ≥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.

Keywords

diabetes mellitus; type 2; naturopathy; hemoglobin a; glycosylated; self efficacy; self care; diet therapy; complementary therapies

BACKGROUND

Clinical risk factor control is poor in patients with Type 2 diabetes 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%)[1]. Increasingly complex pharmaceutical strategies are contributing minimally; only 32% of patients on triple oral therapy (TZD, sulfonylurea, and

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metformin) have an HbA1c less than 7%[1]. 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 0 being physically inactive[2].

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[3,4]. 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 seconds to >6 minutes)[5]. 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%).[7,8] 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[9–11]. Thus rigorous evaluations of the effectiveness of naturopathically delivered healthy lifestyle interventions are needed in more generalized patient populations.

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

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.

Intervention

Table 1 summarizes the key elements of the naturopathic approach to dietary management. The program included a total of 10 hours of active intervention over twelve weeks chosen intentionally to match the “dose” of nutrition and dietitian 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 ensure the principles matched their clinical experiences and the definition was 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[12]. This is presented in Table 2.

The nutrition program was delivered as a combination of one-on-one naturopathic physician-delivered dietary counseling and bi-weekly educational sessions for the entire cohort conducted following potluck-style 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 self-monitored 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[13]. 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 [14]. 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 hours 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, participant-generated 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].

Evaluation

Outcomes included biomarkers and patient-reported outcomes obtained at baseline and week 12. Biomarkers included HbA1c (the primary outcome) and serum lipid profile. Anthropometric measures included blood pressure, height, weight, and calculated BMI. Patients completed 3-day diet diaries from which macronutrient intake was calculated. This is a detailed self-report of amount and type of food and beverage intake collected over 3 consecutive days including a weekend day. Participants were instructed accurate record-keeping using household portion-size measures and records were reviewed by a research associate upon completion to clarify any incongruous entries. Because dietary reporting is subject to reporter bias, standard calculations were made to compare reported dietary energy intake to biologically plausible energy intake based on appropriate Dietary Reference Intake[19].

Patient-reported outcomes included four validated surveys. The Summary of Diabetes Self-Care Activities (SDSCA) questionnaire includes 5 sub-domains of self-care; general diet and specific diet, exercise, medication taking, blood glucose taking and foot care. It has good inter-item correlation: $r = 0.47$ and test-retest correlations: $r = 0.40$. Correlations with other measures of diet and exercise also support the validity of SDSCA subscales (mean = 0.23) [20]. The Problem Areas in Diabetes (PAID) scale measures emotional functioning and resiliency including health attitudes, coping strategies, and social functioning on a 5 point Likert scale. This instrument has good internal consistency ($\alpha = 0.95$) and correlates with measures of general distress ($r = 0.63$), and HbA1c ($r = 0.30$) [21]. The Perceptions about Nutritional Counseling questionnaire measures self-efficacy in making dietary choices and satisfaction with treatment using a 5 point Likert scale. Improvements in dietary factors are associated with decreased HbA1c ($r = -0.34$, $p < .0001$) and BMI ($r = -0.27$, $p = .0002$) [22]. Finally, the Seven Eating Styles Questionnaire assesses seven eating patterns on a 6 point Likert scale that are independently linked to overeating. Based on a 5,256 person survey, the identified factors were found to be consistent and reproducible by randomly splitting the sample and factor analyzing the two separately [23].

Analysis

Self-reported diet was checked for accuracy by calculating plausible caloric intake (within 30%) 3 based on USDA Dietary Reference Intake (DRI) values [19] and nutrient distribution using diet analysis software (Food Processor SQL, ESHA, Salem OR). Three days of diet records were averaged to produce single summary measures per participant per time point. Data analysis was conducted on SPSS for Mac 11.0 (IBM, Somers, NY). Analysis compared pre- and post-measures using paired t-tests for continuous outcome measures and descriptive statistics were calculated. Mean and SD or SEM are reported, except where noted. A p-value of 0.05 or less was accepted as significant.

RESULTS

Twelve participants completed the program and were included in the final analysis. One hundred and thirty-five participants were recruited and phone screened, 29 were eligible for medical screening, 17 were eligible and signed consent forms, 15 began the intervention, and 3 withdrew prior to completing week 12. All three participants who withdrew stated it was due to being too busy to continue. Reported results are per- protocol analyses on the 12 participants who completed the trial. Demographics are presented in Table 3.

Blood sugar control as measured by HbA1c improved significantly over the 12 weeks from a mean $8.1 \pm 0.79\%$ at baseline to $7.7 \pm .99\%$ at week 12 ($p = 0.02$). Although systolic and diastolic blood pressures decreased by 3.1 ± 7.1 mm Hg and 5.5 ± 10.8 mm Hg the changes were not significant. Body Mass Index (BMI) and total cholesterol did not change; mean -0.1 (SD 0.76) 0 kg/m^2 and -3.3 (SD 24.4) mg/dl respectively.

Participants made notable changes in self-reported healthful eating and behavioral modification; results are reported in Table 4. Changes as measured in the Problem Areas in Diabetes composite core improved from a mean 38% to 19% ($p = 0.05$); lower scores signifying fewer problems. Eating behavior was further assessed with the Seven Eating Styles instrument, also included in Table 4. The composite integrated eating score improved significantly ($p = 0.03$). Emotional eating correlated most strongly with higher baseline A1c values ($r = 0.64$, $p = 0.04$).

Adherence to self-management recommendations improved as well (Table 4). Daily blood sugar monitoring increased from a mean 47% of the time to 86% ($p = 0.05$). During this intensive dietary program, participants were asked to monitor their blood sugar multiple

times per day in order to learn to identify relationships between food choices and blood sugar; participant checked blood sugars multiple times as directed 5.3 days/week (from 2.3 days/week originally) ($p=0.04$). “I followed the dietary guidelines provided by the doctor” increased from 1.4 to 3.0 ($p=0.02$) on the scale.

The acceptability of the nutritional approach was good. Agreement with the statement “I would encourage others to follow this diet” had a mean response of 3.9 (4 indicating “strongly agree”). Participation was rated easy on average; 3.6 on a 5-point scale ranging from very difficult to very easy. However, three enrolled participants dropped out before completion of the study because they were “too busy” to attend the physician visits and group sessions. There were no adverse events or side effects during the trial.

DISCUSSION

The evaluation of this pilot program demonstrates that an intensive program of naturopathic-physician-delivered nutritional education is feasible, acceptable to patients, and results in meaningful changes in blood sugar, eating behaviors, and self-management. The naturopathic approach to T2DM management is sometimes criticized as too radical or too difficult for an average patient with T2DM. While participants in this study were self-selecting, most were new to naturopathic medicine and all were new to concepts and food items common to naturopathic nutritional practice. Their experience that these ideas were acceptable, easy, and that they would recommend them to other people with T2DM is suggestive that the naturopathic approach may be effective in a more general audience.

In our study, HbA1c improved by an average of 0.5%, which is clinically meaningful. Other educational and behavioral programs for T2DM been subjected to meta-analysis with effect size estimates suggesting 0.43% reduction in HbA1c is feasible in primary care[24,25]; similarly some oral hypoglycemic agents contribute only about 0.5% HbA1c reduction[26]. Generalization of this finding to a larger population of patients with Type 2 diabetes could have a meaningful impact on patient self-management and clinical outcomes.

This study also focused on what may be unattended dimensions of diabetes nutrition; the underlying eating behaviors that have resulted in dietary patterns that contribute to the development of diabetes[27,28]. The Look AHEAD trial assessed baseline nutritional intake among adults with T2DM and found poor adherence to recommended dietary patterns for calories, fruit and vegetable consumption, saturated fat and sodium intake suggesting that less healthy eating behaviors precede diabetes and “may contribute to increasing their risk of cardiovascular disease and other chronic diseases”[3]. The significant changes in eating behaviors suggest that, by addressing the underlying causes of overeating poor quality foods, participants’ new dietary behaviors may reflect lifestyle changes rather than simply adherence to a formulaic approach to diabetes eating. However, the lack of long term follow-up is a limitation that should be addressed in future larger trials.

While the program focused on nutritional dimensions of diabetes self-care, it is notable that participants also spontaneously increased their physical activity from 1.5 to 5 days a week. This corroborates with research findings that tackling behavioral change on multiple dimensions simultaneously may be superior to a sequential approach in which individual behaviors are counseled on separately. [29,30]. Helping people with T2DM engage in self-management through changes in their overall lifestyle may be more effective than dietary modification alone; indeed these patterns are observed in patients who work with complementary and alternative medicine providers[9,10].

There were some limitations to this study. Despite evidence of strong trends, this study is of limited statistical power to adjust for multiple statistical comparisons; many of the observed

trends may not maintain statistical significance upon Bonferroni or similar correction. We did not have a control group and did not use a randomized design. This study protocol was limited to only the dietary aspects of naturopathic care and excluded other dimensions of naturopathic medicine such as health promotion counseling on physical activity and stress management, use of dietary supplements or botanical medicines, or other modalities that are part of “whole practice” naturopathic medicine[7]. While nutrition was selected because of a priori opinions that nutritional management was the most potent component of the naturopathic approach to T2DM, results may represent a fraction of the benefit that can be expected when a whole practice approach is used. Future studies should investigate whole practice naturopathy.

Finally, these results suggest that nutritional counseling can be successfully and effectively incorporated into primary care, both during the clinical encounter and by using alternative clinical care delivery models e.g. group visits. Health promotion counseling by providers is more effective than outsourcing counseling to a specialist or health coach, in part, because patients view primary care practitioners as the most trusted source of health information[31,32]. Eighty percent of Americans cite their physician as their primary source of information about health[33] and a recent survey found that many patients look to their physicians as their source of nutritional guidance and perceive the level of nutritional expertise of physicians as equal to or just below that of a dietitian[34]. This latter observation contrary to what conventional primary care providers report about their own nutritional expertise[35]. The role of the PCP as counselor for healthy lifestyle change is undeniably important; models of health promotion counseling as delivered in CAM primary care settings may provide a model that could be translated to conventional primary care.

IMPLICATIONS FOR RESEARCH AND PRACTICE

Problems in following diabetes regimens have been well documented; dietary aspects of treatment plans are experienced as the most difficult to follow[4,27]. Because of this, most patients need additional direction and support to implement and maintain dietary change. The ADA recommends that nutrition and dietary advice be delivered by providers expert in this specialty; naturopathic physicians are qualified as such and place strong emphasis on nutrition and health promotion as part of an overall lifestyle strategy[36]. Our research suggests the naturopathic approach to T2DM may be one way to contribute to this growing need for effective risk-lowering interventions. Participants were able to make significant changes in their eating behaviors following a naturopathic nutrition protocol, with corresponding improvements in risk factors. Given economic, social and public health burden of T2DM, and its projected increased prevalence worldwide, this pilot study warrants follow-up in a larger randomized controlled trial or comparative effectiveness trial.

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Table 1**Core Components of Naturopathic Nutrition**

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

Table 2

Overview of Intervention

ADDRESSED AT INDIVIDUAL APPOINTMENTS	ADDRESSED DURING GROUP SESSIONS
<ul style="list-style-type: none"> • Review food record • Goal setting (calculate calorie and carbohydrate targets based on BMI) • Individualize glucose monitoring plan • Individualized functional food prescription (handout) • Problem solving: eating out, understanding blood sugar highs & lows, effects of stress, managing sick days • Revising goals based on BMI changes • Staying motivated 	<ul style="list-style-type: none"> • Overview of whole food nutrition • Reading food labels (sample packages and serving sizes, demonstration of scale, measuring cups & spoons) • Understanding the quality of foods: Glycemic Index, types of fats, carbs, wild & organic foods • Eating behavior presentation and discussion • Problem solving: modifying recipes • Diabetes physiology, staying healthy & avoiding complications

Table 3

Baseline Characteristics and changes in biomarkers

Characteristic	Baseline	Week 12	Significance
Sex (male/female)	7/5 (n=12)		
Age	57 (range 32–67)		
HbA1c	8.1% (SD 0.79)	7.7% (SD 0.99)	P=0.02
BMI	33.1 (SD3.9)	33.0 (SD 3.92)	P=0.7
Systolic BP	143.3 (SD 7.1)	140.1 (SD14.4)	P=0.3
Diastolic BP	84.3 (SD 10.8)	78.7(SD 6.9)	P=0.8
Cholesterol total	162.1 (SD 33.0)	165.4 (SD 33.6)	P=0.6

Table 4

Changes in self-efficacy and self-management behaviors

Behavior	Baseline ($\pm$ SD)	Week 12 ($\pm$ SD)	Significance
Summary of Diabetes Self Care Activities(SCSCA)[20]			
Days out of the last 7 following healthy eating pattern	3.5 $\pm$ 2.0 days	5.3 $\pm$ 0.5 days	p=0.05
Days per week, over the last month, following a healthy eating pattern	3.6 $\pm$ 1.6 days	5.2 $\pm$ 1.2 days	p=0.02
Days out of the last 7 consuming 5+ fruits/vegetables per day	4.5 $\pm$ 1.0 days	5.8 $\pm$ 1.3 days	p=0.01
Days out of the last 7 participating in physical activity	1.8 $\pm$ 2.7 days	5.2 $\pm$ 1.6 days	p=0.02
Frequency of checking blood sugar (% of the time)	47%	85%	p=0.05
Days out of the last 7 checked blood sugar as recommended	2.3 $\pm$ 2.7 days	5.3 $\pm$ 2.1 days	p=0.04
Perceptions About Nutritional Counseling(PANC)[22]			
Average daily carbohydrate intake	51.4%	40.1%	p=0.07
Attention to type of dietary fat consumed	Seldom (2.2 $\pm$ 1.0)	Often (2.8 $\pm$ 0.9)	p=0.04
Know how to follow dietary guidelines	Definitely no (1.4 $\pm$ 1.1)	Yes (3.0 $\pm$.00)	p=0.02
Feel in control of my diabetes	Definitely no (1.1 $\pm$ 0.9)	Yes (3.0 $\pm$.00)	p=0.01
Problem Areas in Diabetes(PAID)[21]			
Feeling scared about living with diabetes	2.5 $\pm$ 1.5	.67 $\pm$.52	p=0.006
Feeling overwhelmed by diabetes	2.2 $\pm$ 1.2	0.3 $\pm$ 0.5	p=0.03
Feeling discouraged about your diabetes treatment plan	2.5 $\pm$ 1.5	.67 $\pm$ 1.2	P=0.06
PAID composite score (lower signifies less problem)	37.9%	19.0%	p=0.05
Seven Eating Styles (7ES)[23]			
Emotional eating	2.7 $\pm$ 0.5	2.0 $\pm$ 0.8	p=0.02
Food fretting	3.0 $\pm$ 0.8	2.8 $\pm$ 0.6	p=0.59
Selecting fast food/fresh food	2.3 $\pm$ 0.7	1.5 $\pm$ 0.8	p=0.05
Attention to sensory/spiritual dimensions of food	3.3 $\pm$ 1.0	2.1 $\pm$ 0.6	p<0.01
Task snacking	2.4 $\pm$ 0.5	2.4 $\pm$ 0.5	p=1.0
Attention to the dining atmosphere	2.8 $\pm$ 0.8	2.2 $\pm$ 0.7	p=0.01
Attention to positive social settings	2.4 $\pm$ 0.6	2.3 $\pm$ 0.5	p=0.68
7 eating styles integrated eating score	19.0 $\pm$ 2.8	15.3 $\pm$ 2.5	P=0.03

Results reported as means $\pm$ standard deviations (SD).

SCSDA scored as number of days per week: 0–7; PANC scored on 5 point Likert scale: *definitely no* to *yes, definitely*; PAID scored on 5 point Likert scale: *not a problem* to *serious problem* (lower scores signify lesser problem); 7ES scored on 6 point Likert scale: *never* to *always*.