

INTEGRATED HEALTHCARE PRACTITIONERS

Integrated Healthcare Practitioners' Dietary and Nutritional Supplement, and Herbal Remedies Management Program

Author: Philip Rouchotas MSc, ND

SUCCESSFUL COMPLETION OF THE QUESTIONS AT THE END OF THIS PAPER HAS BEEN APPROVED FOR CONTINUING EDUCATION BY THE BDDT-N; 1.0 CREDIT NUTRITIONAL MEDICINE AND BY THE CNPBC; ONE CE HOUR.

Diabetes

Diet and Lifestyle- based management- Update 2010.

Diet and lifestyle- based management of type II diabetes has been established as the best first line treatment strategy for some time, and is of tremendous utility as adjunctive therapy in type I diabetes; in outpatient primary care settings, however, pharmacotherapeutic management remains entrenched as the standard of care. The issue does not appear to be one of evidence base. Eloquent, large, well- controlled human clinical trials have reproducibly demonstrated superiority of diet and lifestyle strategies over pharmacotherapeutic interventions. The issue instead appears to revolve around infrastructure. Canada, and other “industrialized” nations simply do not have a healthcare system capable of offering diet and lifestyle as therapy on a population level.

Diet and lifestyle- based management of diabetes has been previously reviewed in this journal (Rouchotas 2008). The following review will provide a brief synopsis of appropriate intervention strategies and their basis. Focus will then shift to what appears to be an exciting shift in paradigm for diabetes management; multiple research trials, across multiple countries, have been conducted or are underway concerning diet and lifestyle for diabetes prevention and treatment. The objective is to create awareness and appreciation for these global efforts. Recognizing the unquestioned superiority of such methods has led to a global shift in mindset of appropriate prevention and treatment. In theory, the collective outcomes of these research initiatives will drive the establishment of infrastructure required to offer such services on national and eventually global levels. The implications are immense: programs targeting diabetes prevention and treatment are ideally suited to also offer solutions for multiple other endemic health concerns such as metabolic syndrome, hypertension, hypercholesterolemia, secondary coronary prevention, polycystic ovary syndrome, and so on...

DIET AND LIFESTYLE- BASED INTERVENTION PLAN

Table 1 summarizes appropriate diet and lifestyle-based intervention strategies for the prevention and treatment of type II diabetes. It is important to note that the recommendations are based on evidence of trials predominantly examining diabetes prevention; magnitude of benefit is equally impressive when implemented by patients with an established diagnosis of diabetes. While the mainstays of the intervention (weight management, physical activity) are applicable to all patients, a successful program must be individualized for each patient in terms of strategies through which the patient may achieve enhanced compliance. Attendance to regular follow- up visits, whether conducted one- on- one or in a group environment, enhances overall compliance with the prescribed program.

The landmark Diabetes Prevention Program (DPP) trial has established the standard for intervention trials in diabetes prevention. The DPP randomized 3234 individuals at very high risk for diabetes to one of three groups; control, metformin, or intensive diet and lifestyle counseling. After three years of follow- up, 28.9%, 21.7%, and 14.4% of participants had developed diabetes in the control, metformin, and lifestyle groups, respectively (Knowler 2002).

*Philip Rouchotas, MSc, ND
Editor-in-Chief,
Integrated Healthcare Practitioners
Associate Professor, Clinical Nutrition,
Canadian College of Naturopathic Medicine*

*60 Bloor Street West, Suite 1106
Toronto, Ontario, Canada M4W 3B8
philip@ihpmagazine.com*

Table 1. Summary of diet and lifestyle- based interventions for management of diabetes

	Recommendation	Basis	Supporting References
Primary outcomes	Achieve and maintain weight loss of 5-7% of initial body weight. Moderate intensity physical activity (ie: brisk walking) no less than 150 minutes per week.	Addresses the underlying cause of the metabolic dysfunction characterizing impaired glucose control in diabetes. Results in reduced fasting blood glucose, reduced HbA1C, reduced risk of progression to type II diabetes among high-risk individuals, as well as reduced risk of cardiovascular complications and all cause death among patients with diabetes.	American Diabetes Association 2008a, Canadian Diabetes Association clinical practice guidelines expert committee 2008, Knowler 2002.
	Modest carbohydrate restriction. Carbohydrate intake target of 25-40% of total caloric intake.	While the Canadian Diabetes Association recommends no less than 45% of calories be derived from carbohydrate, and highlights diets with >60% carbohydrate from low glycemic index/ high fibre sources improve glycemic control, the American Diabetes Association highlights that either low carbohydrate or low fat diets are effective for glycemic control.	American Diabetes Association 2008a, Canadian Diabetes Association clinical practice guidelines expert committee 2008
Secondary Considerations	Carbohydrate sources should be of low glycemic index and be rich in soluble (viscous) fibres. Goal of 14g fibre per 1000kcal of food.	Viscous fibres delay gastric emptying thus slowing the release of glucose from the small intestine. Diets rich in soluble fibre have been shown to reduce HbA1C as well as reduce the number of hypoglycemic episodes.	American Diabetes Association 2008a, Canadian Diabetes Association clinical practice guidelines expert committee 2008.
	Total fat intake should achieve 30-35% of total calories. A significant portion of this should be comprised of olive oil and/ or flax seed oil. Saturated fat, cholesterol, and trans fat intake should be restricted to below 10% of total daily caloric intake, less than 200mg per day, and as close to zero as possible, respectively.	Fat intakes approaching 35% of total caloric intake, rich in oleic and alpha linolenic acid, have contributed to large reductions in all cause mortality among individuals with heart disease. Olive oil has demonstrated the outcome of improved glycemic control in controlled human trials. Olive oil and flax seed oil have demonstrated reduction of fasting LDL-C levels and reduction of blood pressure in controlled human trials. It must be noted that fat restricted diets have shown efficacy in preventing progression to diabetes among high risk individuals.	de Lorgeril 1999. Madigan 2000, Perez-Martinez 2005. Bierenbaum 1993, Cunnane 1995, Ferrara 2000, Kris- Etherton 1999, Perona 2004, Sioen 2009, Takeuchi 2007. Knowler 2002, Tuomilehto 2001.
	Protein should be maintained at 15-20% of total caloric intake. This value may increase modestly if a modest carbohydrate restriction is imposed.	Achieves protein adequacy. Helps maintain compliance with calorically restricted diets.	American Diabetes Association 2008b, Canadian Diabetes Association clinical practice guidelines expert committee 2008.
Tertiary Considerations	Fish oil supplementation at 600- 4000mg combined EPA + DHA. per day.	Reduces risk of all cause mortality and sudden coronary death among individuals with heart disease, and risk of fatal and non fatal major coronary events in otherwise healthy people. Fish oil supplementation has been shown to reduce adverse cardiovascular outcomes among individuals with diabetes.	Mozaffarian 2007. American Diabetes Association 2008b.
	Plant sterol supplementation at 500mg 3-4X per day.	Lowers LDL-C by an average of approximately 14%. Positively reviewed by the American Diabetes Association for individuals with diabetes.	American Diabetes Association 2008b.
	Alpha lipoic acid 300-600mg per day.	Has demonstrated impressive efficacy for preventing and reversing peripheral neuropathy associated with diabetes.	Tankova 2004, Ziegler 2006.
	Lutein 10mg per day	Has demonstrated efficacy in reversing several chronic degenerative diseases of the eyes, and may thus be appropriate for prevention and treatment of diabetic retinopathy.	Bahrami 2006, Olmedilla 2003, Richer 2004.

The question of greatest importance, however, was not addressed by this trial... The obvious and appropriate criticism of lifestyle intervention is lack of compliance; the above- stated outcomes were not produced among compliant participants, but represent the outcome among all individuals randomized to lifestyle counseling; what percentage of participants who actually complied with lifestyle counseling went on to develop diabetes?

The Finish Diabetes Prevention Program (Tuomilehto 2001) addressed this important and pressing question. The trial randomized 522 individuals at high risk for developing diabetes to control of lifestyle counseling with four years of follow- up. The control group received a handout outlining the identical strategies counseled to the lifestyle intervention group. After four years of follow- up, 23% of individuals in the control group and 11% of individuals in the lifestyle group went on to develop diabetes.

The trial went on to assign each participant, in both the control and lifestyle groups, a compliance score. The trial identified five key goals; Goal 1: Wt loss 5%. Goal 2: fat<30% calories. Goal 3: Sat fat <10% calories. Goal 4: fiber 15g/ 1000kcal. Goal 5: moderate exercise 30min per day. Participants were then divided based on number of goals achieved. Among participants achieving four or five of the five predefined goals, the percentage of individuals who went on to develop diabetes was zero. Not a single participant achieving four or five of the predefined five goals developed diabetes (Tuomilehto 2001). This represented approximately 20% of participants assigned to the intensive lifestyle counseling group, and approximately 6% of participants in the control group. It is inspiring to note that a small subset of participants in the control group (6%) were able to achieve lifestyle changes sufficient to completely ward of diabetes by receiving no other intervention than a handout describing healthful lifestyle suggestions!

RECENT GLOBAL INITIATIVES ATTEMPTING TO REPLICATE THE ABOVE OUTCOMES; ADDRESSING ETHNIC INDIVIDUALITY, AND FEASIBILITY

The Diet, Obesity, and Genes (Diogenes) Study

Larsen (2010) and Moore (2010) report the ongoing Diogenes study, a large RCT being conducted across eight European nations. A total of 891 families with at least one overweight or obese parent have been screened, and those eligible have undertaken an 8-week weight-loss phase with a fixed low-energy diet (800 kcal). Those families in which at least one parent has attained a weight loss of $\geq 8\%$ during this phase (weight loss), have then been randomized to one of five energy ad libitum, low-fat (25-30 E%) diets for 6 or 12 months to study weight maintenance: low protein/low glycemic index, low protein/high glycemic index, high protein/low glycemic index, high protein/high glycemic index or

control (national dietary guidelines) to assess weight re-gain. The median weight loss during the low-calorie diet was 10.3 kg (interquartile range: 8.7-12.8 kg, n = 775). A total of 773 adults and 784 children have now been randomized to the 6-month weight regain prevention phase.

Look AHEAD (Action for Health and Diabetes) Trial

Albu (2010) and Redmon (2010) report on the Look AHEAD trial, a multicenter RCT including 5145 overweight or obese adults with type 2 diabetes in an intensive lifestyle program involving group and individual meetings to achieve weight loss through caloric restriction and exercise. Control subjects were given a standard diabetes education program. At one year, the average number of medications used to treat cardiovascular risk factors decreased to 3.1 in the intervention group, compared to 3.6 in the control group ($p < 0.0001$). Estimated monthly costs of cardiovascular medications were \$143 and \$173 respectively ($p < 0.0001$). Weight and fasting glucose decreased significantly ($p < 0.0001$), and this was greater in men (12 vs 8% and 16 vs 7% respectively). Free fatty acids during hyperinsulinemia decreased and glucose disposal rate increased significantly in men and women (53 vs 41% and 63 vs 43% respectively).

Smaller Additional Studies

Garnett (2010) developed a multicenter RCT known as the RESIST trial in Australia. A total of 108 adolescents with insulin resistance or prediabetes will be given metformin plus a diet and exercise program utilizing one of two diets: a low-fat, high carb, or a moderate-carb, higher-protein diet. Participants are supervised by dietitians and personal trainers for an intensive 3-mo period, and then managed for 6 months by their usual physician or study clinician to measure longer term effectiveness. Insulin sensitivity will be measured at 3, 6, and 12 months.

Eriksson (2010) conducted the Bjorknas Study RCT in Sweden. A total of 151 adults at moderate to high risk of cardiovascular disease were given a diet and lifestyle intervention plus standard care, or standard care alone. The intervention consisted of supervised exercise sessions and diet counseling for 3 mo, then group meetings for 3 mo. The intervention group reported increased quality of life and was found to be cost-effective, with \$47 net savings per participant, and up to \$4800 per quality-adjusted life years (QALYs).

Hofso (2010) conducted a controlled clinical trial in Norway comparing gastric bypass surgery to lifestyle modification. A total of 146 morbidly obese subjects of mean BMI 45.1 were given either gastric bypass surgery or intensive dietary and lifestyle intervention for 1 yr. At one year, weight loss was 30% in the surgery group and 8% in the lifestyle group. Remission of type 2 diabetes and hypertension was

significantly greater in the surgery group than the lifestyle group but occurred in both: 70 vs 33% ($p=0.027$), and 49 vs 23% ($p=0.016$). Benefits were seen in both groups with respect to glucose metabolism, blood pressure, lipids, and inflammatory markers.

Coppel 2010 conducted the LOADD trial, an RCT, in New Zealand. A total of 93 adults with type 2 diabetes and HgbA1C $>7\%$ despite drug therapy, plus 2 of: overweight or obesity, hypertension, and dyslipidemia were given dietary counseling for 6 months plus usual care or usual care alone. There was a highly significant 0.4% decrease in HgbA1C at 6 months (95%CI -0.7 to -0.1%, $p=0.007$), in addition to significant decreases in weight (-1.3kg), BMI (-0.5), and waist circumference (-1.6cm) in the group receiving counseling versus usual care alone.

Helmink (2010) developed the Dutch exercise therapy trial (“BewegKuur” study) for patients with diabetes and prediabetes. A lifestyle advisor, usually a nurse or physiotherapist, designs and supervises an individualized exercise regime that can be carried out at existing local exercise facilities or under the supervision of an exercise coach or physiotherapist. All participants are also referred to a dietician for group education. The program was piloted in seven centers in 2008, with the aim of implementing it nationally by 2012.

Harati (2010) conducted a cluster-controlled trial of diet and lifestyle in Iran. A total of 3098 intervention group and 5114 control group individuals were examined, of which 58% completed follow up 3-4 years later. The intervention aimed to improve diet, exercise, and smoking habits, through educational interviews, lectures, and publications. The incidence of diabetes in the intervention group was 8.2 per 1000-person-years, compared to 12.2 in the control group, RR 0.65 (95%CI 0.30-0.83). Other significant outcomes were: weight loss of 0.5kg and BMI reduction of 0.18 kg/m² in men, and decreased waist circumference by 1.0cm in women, systolic and diastolic BP reductions of 1.1 and 0.6 mmHg respectively in women; and reductions in fasting glucose, 2-hr glucose, total cholesterol, triglyceride, and increased HDL.

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Qiao (2010) developed a Chinese diabetes prevention program consisting of training for healthcare providers followed by delivery of lifestyle counseling targeting individuals at increased risk of diabetes. A subset of 12,000 patients will be randomly selected for analysis.

In addition to these, many more related studies have been conducted by Ackermann (2008), Arsand (2010), Izquierdo (2010), Ferdowsian (2010), Foster (2010), Goodpaster (2010), Katula (2010), Ma (2009), Ma (2010), Parikh (2010), Seidel (2008), Singhal (2010), Whittemore (2009), Whycherley (2010) and others.

Similar initiatives have been conducted or are ongoing in other populations of significant importance: Asbee (2009) and Oostdam (2009) have examined lifestyle intervention for prevention of gestational diabetes. Foster (2010) conducted an RTC of a school-based program for overweight/obese children.

CONCLUSION

The role of diet and lifestyle- based intervention as the primary care standard for the prevention and treatment of type II diabetes, and as important adjunctive care in type I diabetes, has been well established among the published literature for many years. Practitioners working in the field have invariably felt frustration at the preference of primary care professionals to utilize pharmacotherapy as first- line therapy. It appears as though widespread change is coming...

The superiority of diet and lifestyle over pharmacotherapy for diabetes management has and continues to be reproduced across multiple intervention trials. The global nature of research in the area reinforces the immense need of a better solution to a rapidly growing epidemic. Whether through one- on- one consultation, group meetings, telemedicine, e-medicine, or any other system of delivery, there appears to be a global shift in mindset concerning diabetes management. The most exciting aspect of these ongoing initiatives is the potential for their broader application; once established for diabetes management, identical systems will invariably become entrenched as primary care standard for management of established cardiovascular disease, as well as management of traditional cardiovascular disease risk factors. ■

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Questions

1. The Diabetes Prevention Program as reported by Knowler (2002) demonstrated a dose response relationship between compliance with diet and lifestyle modification and risk of developing type 2 diabetes.
 - A. True
 - B. False

2. 6% of patients in the control group of the Finnish Diabetes Prevention Program achieved compliance with 4 or 5 of the five prespecified treatment goals (Tuomilehto 2001). Among this subset of individuals, the percentage that developed type 2 diabetes was
 - A. 23%
 - B. 11%
 - C. 5%
 - D. 0%

3. Lutein at a dose of 10mg per day has been shown in controlled human intervention trials to prevent and reverse diabetic retinopathy.
 - A. True
 - B. False

4. The most appropriate basis for supplementation with alpha lipoic acid in diabetes is
 - A. Improving antioxidant status
 - B. Reducing risk of sudden coronary death
 - C. Reducing risk of stroke
 - D. Treatment of peripheral neuropathy

5. The most important outcome when managing type 2 diabetes is
 - A. achieving greater than 60% of caloric intake from carbohydrates of low glycemic, high fibre sources
 - B. achieving less than 30% of total calories from fat
 - C. achieving loss of 5-7% of initial body weight and maintaining 150 minutes/ wk of moderate intensity physical activity
 - D. achieving 15-20% of total caloric intake from lean protein sources.

6. Since the initial success of the Diabetes Prevention Program, there have been many new initiatives seeking to implement such programs on a nationwide level. Diogenes is a pan-European trial that seeks to:
 - A. Study weight loss in families with at least one overweight/ obese parent
 - B. Help these parents attain weight loss of $\geq 8\%$ with a low calorie diet
 - C. Study the effects of diet on weight maintenance
 - D. All of the above

7. The Look AHEAD trial found that an intensive diet and lifestyle program was able to significantly decrease weight, fasting glucose, and the number of medications needed to treat cardiovascular risk factors, compared to standard diabetes education.
 - A. True
 - B. False

8. Erikson (2010) found that an intensive diet and exercise program increased participants' quality of life and was found to be cost-effective, with \$47 net savings per participant.
 - A. True
 - B. False

9. Asbee (2009) and Oostdam (2009) have developed lifestyle based programs for the prevention of gestational diabetes and excessive weight gain during pregnancy.
 - A. Asbee (2009) found the program effective in reducing weight gain but not gestational diabetes
 - B. Oostdam (2009) found the program effective for preventing gestational diabetes
 - C. Neither of the above
 - D. All of the above

10. HEALTHY is a US-based study conducted in school children. Schools who ran a multi-component prevention and assessment program were able to achieve improvements in:
 - A. BMI score
 - B. Fasting insulin levels
 - C. Prevalence of obesity
 - D. All of the above

FAX OR EMAIL ANSWERS TO:
 416.703.6392
 philip@ihpmagazine.com