I, Cynthia G Rutherford, hereby submit this original work as part of the requirements for the degree of Master of Science in Epidemiology (Environmental Health).

It is entitled:
Cost Effective Analysis of Lifestyle Interventions Versus Standard Treatment In Patients With Type 2 Diabetes: A Literature Review

Student's name:       Cynthia G Rutherford

This work and its defense approved by:

Committee chair:  Erin Nicole Haynes, Ph.D.

Committee member:  Mark Eckman, M.D.
Cost Effective Analysis of Lifestyle Interventions Versus Standard Treatment In Patients With Type 2 Diabetes: A Literature Review

A thesis submitted to the
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Cynthia Rutherford
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Committee Chair: Erin N. Haynes, DrPH, MS
Abstract

There are 25.8 million children and adults in the United States, 8.3% of them have diabetes. Twenty five point six million, or 11.3% of all people 20 years or older have diabetes. Type 2 diabetes accounts for 90 to 95% of diabetes cases in the United States. Type 2 diabetes runs in families. In part, this tendency is due to children learning bad habits eating a poor diet, not exercising from their parents; however there is also a genetic basis. Risk factors for Type 2 diabetes include excess body fat, physical inactivity, and smoking. A determination of Body Mass Index (a calculation of your height and weight) will indicate if a person is overweight or obese. The U.S. Department of Health and Human Services indicates that a BMI of 25 to 30 is considered overweight and over 30 is considered obese. With every 1 increase in BMI, the risk of developing type 2 diabetes increases by 10 to 30%. Diabetes is also the leading cause of kidney failure, nontraumatic lower-limb amputations, and new cases of blindness among adults in the United States. Diabetes is a major cause of heart disease and stroke, and is the seventh leading cause of death in the United States.

Diabetes type 2 a serious epidemic in the United States that, with lifestyle interventions, can be reduced. Type 2 diabetes is becoming more common due to increasing obesity and failure to exercise. Diet and exercise are key factors in reducing the amount of body fat, which is a main risk factor in type 2 diabetes. Studies have shown that increased activity and better choices of foods in the diet can reduce or even eliminate type 2 diabetes.

The average median annual direct medical costs of non-insulin dependent type 2 diabetes is $1,700 to $2,100 per person with no microvascular, neuropathic, or cardiovascular complications.
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Introduction

Diabetes Mellitus, is a chronic disease that occurs when the pancreas does not produce enough insulin or when the body does not effectively use the insulin it produces. Insulin is a hormone that regulates blood glucose (blood sugar). The effect of uncontrolled diabetes is hyperglycemia (increased blood sugar), which if not managed effectively over time, will severely damage many organs and organ systems, especially the nerves and blood vessels. Every 7 seconds, one person dies of diabetes in the world, according to the International Diabetes Federation. That's more than AIDS and malaria combined. In 2010, four million people died from diabetes, or 6.8% of global mortality (Roglic, Unwin, 2010). Diabetes is present in low and middle income countries where the total diagnosed cases are 70%. However, we consider that more than a third of people are unaware of their condition (Sherwood,2008). There are 25.8 million children and adults in the United States, 8.3% of them have diabetes (Lamotte, 2002). Twenty five point six million, or 11.3 % of all people 20 years or older have diabetes (Lamotte, 2002). Type 2 diabetes accounts for 90 to 95% of diabetes cases in the United States (American Diabetes Association, 2008). Diabetes is associated with significant health care costs (Sidorov,2002). It has been estimated to affect 16 million Americans, with $44 billion a year in direct medical and treatment costs (Sidorov,2002). Type 2 diabetes runs in families, in part, this tendency is due to children learning bad habits eating a poor diet, not exercising from their parents; however there is also a genetic basis (American Diabetes Association, 2008). Risk factors for Type 2 diabetes include excess body fat, physical inactivity, and smoking (Bruggen, et al., 2007). A determination of Body Mass Index (a calculation of your height and weight) will indicate if a person is overweight or obese. Several studies have shown a positive association between obesity and an increased rate of death, with an even greater risk of death among persons with a body-mass index of 35 or more, as compared with those with a BMI of 30 to 34 (Adams TD, Gress RE, et al. ,2007). The U.S. Department of Health and Human Services indicates that a BMI of 25 to 30 is considered overweight and over 30 is considered obese. With every 1 increase in BMI, the risk of developing type 2 diabetes increases by 10 to 30% (Bruggen, et al., 2007). Diabetes is also the leading cause of kidney failure, non-traumatic lower-limb amputations, and new cases of blindness among adults in the United States. Diabetes is a major cause of heart disease and stroke, and is the seventh leading cause of death in the United States (American Diabetes Association, 2008).
Diabetes type 2 is a serious epidemic in the United States that, with lifestyle interventions, can be reduced. Type 2 diabetes is becoming more common due to increasing obesity and failure to exercise (American Diabetes Association, 2008). Diet and exercise (American Diabetes Association, 2008; Jakicic, 2003; Blissmer, Riebe et al., 2006) are key factors in reducing the amount of body fat, which is a main risk factor in type 2 diabetes. Studies (The Look AHEAD Research Group, 2010) have shown that increased activity and better choices of foods in the diet can reduce or even eliminate type 2 diabetes. It has been estimated that an 11 pound weight loss over time could reduce the risk of diabetes by 55% over 3.2 years of follow-up (Hamman, Edelstein, et al., 2006). This suggests that people who lose even more weight, with physical activity and meeting dietary fat goals, could reduce their diabetes risk by more than 90% (Hamman, Edelstein, et al., 2006). Lifestyle changes have been shown to be even more effective than Metformin therapy (The Diabetes Prevention Program (DPP) Research Group, 2002). Inadequate physical activity is one of the most difficult and prevalent problems that substantially contributes to poor health in the United States (M. Cody, et al., 2002). Only 22% of adults in the US meet the recommended leisure time physical activity levels for health benefits as defined by the objectives of Healthy People 2000, while another 54% of adults are inadequately active and another 24% are completely sedentary (M. Cody, et al., 2002). Physical activity can improve blood lipid profiles, improve glucose control, lower blood pressure, decrease the risk of adverse cardiovascular events, and decrease the risk of death among people with type 2 diabetes (Richardson, Mehari, et al., 2007). Results suggest that moderate to high doses of exercise in combination with a restricted calorie intake results in 8-10% reductions in body weight over 12 months (Jakicic, 2003). The Diabetes Prevention Program (DPP), a 27-centered randomized clinical trial, reported a 58% reduction in the incidence of diabetes over almost 3 years in subjects treated with an intensive lifestyle intervention (Hamman, Edelstein, et al., 2006) which included diet and exercise. Literature has also supported that even a small weight reduction often leads to significant improvements in health-related quality of life (Blissmer, Riebe, et al., 2006). Previous studies have shown that other disease prevention methods are cost-effective versus the corresponding therapeutic health care, and sometimes even producing a cost savings (Hatzianastassiou, et al., 1988). Screening for pre-diabetes in the overweight and obese U.S. population followed by the DPP lifestyle intervention has a relatively attractive cost-effectiveness ratio (Hoerger TJ, Hicks KA, et al. 2007).

Standard therapy assessments and laboratory tests for Type 2 diabetes include, but are not limited to the following: Hba1c, glucose, retinopathy, nephropathy, neuropathy, cerebrovascular
disease, cardiovascular disease, peripheral vascular disease, hypertension, hypercholesterolemia, and
tobacco cessation (American Diabetes Association, 2008). Insulin-dependent diabetics can develop
nonproliferative retinopathy and 62% develop proliferative retinopathy (The Diabetes Control and
Complications Trial Research Group, 1996). The leading cause of blindness among adults 20-74 is
diabetes (American Diabetes Association, 2008). Twenty eight percent of people with insulin-dependent
diabetes may experience severe vision loss, even with the availability of laser therapy (The Diabetes
Control and Complications Trial Research Group, 1996). Insulin dependent diabetics require daily self-
monitoring, which consists of 1 or 2 insulin injections per day (The Diabetes Control and Complications
Trial Research Group, 1996). People with diabetes are also 76% more prevalent to have cardiovascular
disease. There is twice the risk for coronary heart disease and stroke for people with type 2 diabetes
(American Diabetes Association, 2008). Diabetes related deaths, among people ≥65 years in 2004, were
related to heart disease on 68% of the death certificates and stroke on 16% of death certificates
(American Diabetes Association, 2008). Hypertension was a factor in 67% of diabetic adults ≥20 in 2005-
2008 (American Diabetes Association, 2008). Forty four percent of new cases of diabetes related kidney
failure were found in 2008 (American Diabetes Association, 2008). Diabetes is the leading cause of
kidney failure, with 202,290 diabetics with end-stage kidney disease on dialysis or with a kidney
transplant (American Diabetes Association, 2008). Neuropathy occurs in approximately 60-70% of
diabetics (American Diabetes Association, 2008). Diabetes also accounts for 60% of lower-limb
amputations (American Diabetes Association, 2008). Diabetes contributed as an underlying cause or
contributing factor to 231,404 deaths in 2007 (American Diabetes Association, 2008).

According to Hamman and colleagues (2006), the most important part of diabetes treatment
and prevention of late complications is diet. In the early stages of type 2 diabetes diet change can
reduce or eliminate the need for medication. Just as in healthy people, its main purpose is to provide
the right amount of nutrients and energy (particularly carbohydrates) and ensure proper hydration.
Therefore, meals with diabetes need to be varied. The diabetic diet is dominated by foods that do not
cause an excessive increase in blood glucose and allows keeping a healthy weight. This effect is achieved
by appropriate selection of products, eating meals at regular times, but in smaller portions. The diabetic
diet must be adapted to the needs of the individual patient in calories and nutrients, which is dependent
on the age, body weight, led lifestyle and other conditions (such as pregnancy, breast feeding,
accompanying diseases) and the additional risk factors (Blissmer, Riebe, et al., 2006). For people with
diabetes, it is important to control the amount of carbohydrates inested. As a result, the diabetics diet
provides them with the correct nutrition to keep blood glucose at a level close to the normal range, and allows one to maintain proper weight loss and prevention of diabetes complications (e.g. by normalizing lipid levels) (Richardson, Mehari, et al., 2007). A strategy of intensive glucose control that lowered the glycated hemoglobin value to 6.5% yielded a 10% relative reduction in the combined outcome of major macrovascular and microvascular events, primarily as a consequence of a 21% relative reduction in nephropathy (Patel A, MacMahon S, et al. 2008). Morbidity associated with long-term microvascular and neuropathic complications can be substantially reduced by interventions that achieve glucose levels close to the nondiabetic range (Nathan DM, Buse JB, et al. 2009).

Moderate physical activity is particularly important in the treatment of type 2 diabetes, which is often caused by being overweight or obese. In this case, physical activity is a major factor in achieving and maintaining a healthy weight by spending excess energy. Reducing the weight and increase in physical activity leads to an increase in insulin sensitivity, improve the lipid profile (reduce serum triglycerides and LDL, while increasing HDL) and promotes the reduction of blood pressure, thereby reducing the risk factors for diseases of the cardiovascular system (American Diabetes Association, 2008). The result is an improvement in glycemic control, reducing the need for medication (reduction in the number of drugs or their doses) and a delay in the development of certain complications of diabetes or to prevent their occurrence. Most preferred is a daily half-hour of an aerobic exercise, such as walking, cycling or swimming (Helmink, Meis, et al., 2010).

**Diabetes Intervention Methods**

**Standard Therapy Methods**

In light of a research published in an online edition of New England Journal, surgery is important and more effective at treating people with severe type 2 diabetes than the standard medical treatment (The Diabetes Prevention Research Group, 2002). The very first type of study was carried out by the researchers from the New York-Presbyterian/Weill Cornell Medical Center. It was found by the researchers that many of the study participants who received bariatric surgery were finally able to stop taking diabetes medication and also ensures remission of the disease for about two years of study period as compared with the Zero participants in the standard medical treatment group.

In the primary prospective analysis of 753 overweight patients randomly assigned metformin or dietary treatment after diagnosis of type 2 diabetes in the UKPDS, metformin was associated with a 39%
relative risk reduction in myocardial infarction ($p=0.010$) and 36% relative risk reduction in all-cause mortality ($p=0.011$), effects not thought to be mediated through established risk factors. Metformin is the only antidiabetic agent that has been shown definitively to reduce macrovascular risk in overweight type 2 diabetic patients and it remains the first-line agent of choice recommended by most treatment guidelines (Dormandy JA, Charbonnel B, et al. 2005). Progressive deterioration of diabetes control was such that after 3 years approximately 50% of patients could attain the goal of HbAC < 7 with monotherapy, and by 9 years this declined to approximately 25% (Turner RC, Cull CA, et al. 1999).

**Lifestyle Interventions**

Lifestyle intervention for diabetes prevention programs is a multidimensional process with a series of health promotion strategies at multiple levels. The complexity of diabetes prevention programs necessitates a comprehensive and integrated indicator to evaluate their efficacy. Unlike the weight loss, the components of metabolic syndrome provide a multivariate parameter which covers more aspects of risk reduction caused by lifestyle intervention (Nathan, Cleary, et al., 2005). A metabolic syndrome index is a systematic and comprehensive indicator that can be used to evaluate the efficacy of diabetes prevention programs because it measures risk reduction for diabetes and its complications at multiple levels and dimensions. A reduction in the metabolic syndrome index reflects the risk reduction for diabetes and its complications resulting from a diabetes prevention program, which makes program-to-program comparison possible. In addition, the five components of the metabolic syndrome index, to some extent represent different aspects of the risk for diabetes and its complications. The magnitude of change in the five components outlines the strengths and weaknesses of a program, which can serve as a useful reference for researchers to choose the best program for specific populations (Reichard, Nilsson, Rosenqvist, 1993).

The Diabetes Prevention Research Group is an honors-heavy group of diabetes researchers from around the world, many of whom are associated with the Northwestern University Center for Endocrinology in Chicago, IL. Saha and colleagues (2010) hypothesized that modifying factors such as chronic fasting, after-meal blood glucose levels (through the diabetes drug metformin), and a more active lifestyle would prevent or delay the development of diabetes.
Among other findings, the Saha and colleagues (2010) discovered through a retrospective written questionnaire of subjects in its research group that lifestyle modification resulted in a reduction of the incidence of type 2 diabetes by 58%. The addition of the diabetes drug metformin to the treatment regimen further reduced occurrences by 31%. The researchers concluded: “Lifestyle changes and treatment with metformin both reduced the incidence of diabetes in persons at high risk” (Narayan, Williamson, 2010). Whereas the management and treatment approaches are clearly beneficial for prediabetes, the consequences of doing nothing are equally true. Despite this knowledge, less than half of the individuals diagnosed with prediabetes follow their treatment plan and manage their HbA1c level within a healthy range (Franz, Bantle, et al., 2002). HbA1c occurs when glucose sticks to hemoglobin in the blood, forming a glycosylated hemoglobin molecule, also known as HbA1c. The more glucose found in the blood, the more HbA1c will be present. Providers conduct HbA1c tests on the blood of their diabetic patients to assess how well they managed the disease during the previous 2 to 3 months.

Physical Activity and Healthcare Management

Accumulated scientific evidence has indicated that physical activity will bring positive and broad-ranging health benefits throughout an individual’s lifespan (Franz, Barry, et al., 1995). Observational studies have demonstrated that lack of physical activity is a risk factor for loss of function, all-cause mortality, and a variety of chronic diseases including heart disease, type II diabetes, and hypertension. Many social and behavioral science theories have been developed and implemented to guide health-promotion interventions for promoting physical activity. The transtheoretical model (TTM) is one of the widely applied theories.

Examining stages of change for a healthy behavior longitudinally results in many possible patterns of stages of change (Franz, Warshaw, et al., 2003). For example, if we record the stage of change in physical activity at three time points, where each time point has five stages of change, then there will be 5x5x5=125 different longitudinal patterns. It is cumbersome and difficult to describe and present the big picture of the longitudinal patterns of stages of change when we have 125 different patterns (Vinicor, 1998). To date, however, no studies have tried to use statistical methods to reduce the dimensions of data and investigate whether a smaller number of meaningful longitudinal patterns exist among the numerous stages of change patterns.
Most type 2 diabetics spend less time on maintaining a healthy body weight, keeping proper
diet and exercise. A study was done to understand the impact of lifestyle on the onset of diabetes.
Americans aged 50-71 years, completed a detailed questionnaire about their life style. At this time, none
of the persons participating in the study were suffering from diabetes. After 10 years they were
subjected to further tests. This time they were not only asked about the lifestyle, but also about health
and illness. It turned out that after decades, diabetes was diagnosed in almost 10 percent men and
more than 7 percent women. The least frequently diagnosed with diabetes were women who complied
with all basic guidelines, ate a high fiber products, and exercised at least 20 minutes three times a week.
It has been calculated that the risk of diabetes in these patients was about 84 percent less. Men who
cared about health were about 72 percent less prone to disease. Among all respondents the most
important risk factors proved to be maintaining a proper body weight. The report shows weight
management as much as 60-70 percent reduces the risk of diabetes. Individuals who are overweight,
but observe a rich diet in vegetables and fruits, and in addition are active are less likely to have
diabetes.

Movement is important mainly because of the need to reduce weight. Obesity is a major risk
factor for type II diabetes. It has been proven scientifically that too much weight is a catalyst for the
process of production of insulin resistance in the cells of the body. The most radical diet combined with
exercise sets are focused on weight reduction in the rate of more than 2.2 pounds per week or
production shortage of calories in excess of one million per day (1.000kcal).

The first rule of a diabetic diet is calorie counting. Even if people do not have to specifically lose
weight, they must take care not to gain weight. The point is to replace them with complex
carbohydrates that do not get into the blood quickly and do not cause drastic fluctuations in the
concentration of glucose. In addition to the need to count carbohydrates calories, it is understood that
the daily intake should be at the level of 160-400 g, depending on physical activity. Too much of a good
thing, but for a small number of them, will force the body to produce carbohydrates from protein and
fat, which will be accompanied by the release of dangerous ketones in large quantities causing extreme
life-threatening coma. Fat can influence the formation of atherosclerosis, which is also one of the
complications of diabetes. The complications of diabetes account for substantial costs, with
management of macrovascular disease being the largest and earliest. If improving glycemic control
prevents complications, it will reduce these costs (Caro JJ, Ward AJ, et al. 2002).
Self-efficacy is an important mediating mechanism in advancing understanding of the treatment of obesity. This study developed and validated the Weight Efficacy Life-Style Questionnaire (WEL), improving on previous studies by the use of clinical populations, cross-validation of the initial factor analysis, exploration of the best fitting theoretical model of self-efficacy, and examination of change in treatment. The resulting 20-item WEL consists of five situational factors: Negative Emotions, Availability, Social Pressure, Physical Discomfort, and Positive Activities. A hierarchical model was found to provide the best fit to the data. Results from two separate clinical treatment studies (total N = 382) show that the WEL is sensitive to changes in global scores as well as to a subset of the five situational factor scores. Treatment programs may be incomplete if they change only a subset of the situational dimensions of self-efficacy (Clark MM, Abrams DB, et al. 1991). A comprehensive setting approach with educative, somatic, psychosocial and activity therapeutic components are recommended for prevention (Korczak D, Dietl M, et al. 2011).

Research on Cost Analysis

The research conducted by Lamotte, (2002) suggests that use of diet and exercise to cope with the diabetes type 2 disease was more cost effective than using medication. The study was published in diabetes care. The lifestyle intervention incident of 58% was compared with the intervention group of 31% taking metformin which is a drug that is used for diabetes. The lifestyle intervention normally provided better results and it was also cheap. The 10 year study about the people at high risk of diabetes found that the lifestyle intervention was cost effective and metformin cost more than the lifestyle intervention.

According to this research carried out by Cody, et al. (2002), pre diabetes screening is followed by exercise and diet or metformin treatment is cost effective and is required to be considered for the incorporation into current practice. Recognizing these benefits, considerable effort has been invested by health care systems in attempts to engage patients in greater self-management. However, traditional approaches, such as diabetes education, tend to suffer from low patient participation rates and often are not coordinated with the rest of a patient’s medical care. Health coaching expands beyond diabetes education and focuses on activating patients with Type II diabetes on a variety of health behaviors; however, such coaching is often provided by outside service providers contracted by insurance.
organizations and who are not integrated with the patient's health care team. We propose that using clinic-based staff, trained to address psychological aspects of chronic illness, uniquely positions them to work with a PCP and proactively reach out to patients to initiate self-management behaviors through the promotion of SDM. Also, it was concluded that behavioral interventions increased free-living PA/exercise and produced clinically significant improvements in long-term glucose control (Avery, L., Flynn, D., et al., 2012)

Two recent areas of advancement increase the promotion of SDM and patient self-management (Vinicor, 1998). First, information technology and the expanding use of electronic medical records (EMRs) have allowed providers to more efficiently use patient registries for health management of their patient population. Appropriately, identifying and targeting patients in need of intervention improves efficiency. Second, the growing presence of collaborative care (integrating behavioral health providers into the primary care office) improves patient access to services and coordination of interrelated health issues (The Diabetes Prevention Research Group, 2002). Collaborative care often includes professionals, such as health psychologists who are specifically trained in methods to increase motivation and promote healthy behaviors. Collaborative care is a core element of a patient-centered medical home and may provide the optimum method by which increased SDM will occur in primary care.

Given improved technology for patient population management and the increased presence of collaborative care, it is important to assess the impact of connecting these two developments in the activation of patients. The research hypothesis is that collaborative care therapists acting as health coaches can, with relatively minimal effort, increase initial patient self-management behaviors, such as viewing a video they have been asked to watch by their PCP and meeting with their PCP to discuss management of their diabetes (Brandle, Michael, et al., 2003). Such behaviors are seen as preliminary to other self-management behaviors, such as dietary changes and increases in physical activity. Collaborative care therapists serving as health coaches will use patient registries and an outreach approach to invite patients, identified by their physician as having Type II diabetes, to view a decision aid video on diabetes. Subsequent patient behavior will be compared with patients receiving usual care. Outcomes of interest include patient video-viewing behavior, patient visits to the clinic to discuss diabetes with their physician, frequency of diabetes-relevant laboratory work, and frequency of patient referral to diabetes-support services (i.e., group medical visits, consultation by a certified diabetes educator) (Culyer, 2001). It has been noted that group therapy produces greater weight loss (thus more
cost effective) than individual therapy, even among those clients who express a preference for individual treatment (Renjilian DA, Perri MG, et al. 2001).

In this controlled trial by Bruggen, et al., (2007), family physicians were consented and block randomized (by clinic) to either usual care (n = 10) or intervention (n = 11). Usual care allowed physicians to use available clinical tools such as patient registry software and a diabetes decision aid video, which could be prescribed for the patient via the clinic’s EMR. Usual care also allowed referral of patient to collaborative care therapists but not specifically for helping diabetic patients increase self-management behaviors. This project was approved by the University of California San Diego (UCSD) Human Research Protection Program.

Each health coach worked closely with a physician for each study cycle. Together they developed criteria to determine which of the physician’s diabetic patients would receive outreach. While this meant that patients were not randomly assigned to group (i.e., nonequivalent A1c levels between physicians), it reflected an emphasis on getting each physician to actively engage in the intervention and more accurately reflect the process as it would be implemented in real clinical settings. Each physician-health coach dyad in the intervention arm worked together for 60 days. During this period, each health coach met with his or her assigned physician, reviewed patients identified in the physician’s registry, created a plan for whom to provide outreach (e.g., all patients with A1c > 8.5), and managed the mailing and phone calls to patients.

Patients in the comparison group were randomly selected from the patient panels of physicians in the usual care group. Because the intervention was designed to be seen as part of clinical care, and not meant to impose on a physician’s autonomy, physicians in the intervention group were given complete control of setting criteria for patient selection from their own patient panels (e.g., some PCPs selected patients with high blood sugars, others selected patients not seen in their clinic for extended time periods, etc.). Therefore, patients seen by usual care physicians were randomly selected rather than matching them based on disease severity or other parameters to patients seen in the intervention group. It is assumed that by not matching patients, greater disease severity will be observed in the patients followed in the intervention arm, because disease severity was a criteria used by many of the participating physicians to identify patients for outreach. Outcomes were compared across the three
Research has demonstrated that increasing patient self-management skills can improve patient outcomes in Type II diabetes (Sidorov, 2002). While traditional diabetes education is often insufficient to change patients’ health behaviors, SDM is an approach that actively engages the patient in decisions about their own disease management. SDM between the patient and physician can promote patient self-management and has been shown to increase patient satisfaction, as well as decisional quality on a variety of health care issues (Crawford et al., 2002; O’Connor, et al., 2003), yet tools that promote SDM are underutilized by physicians and patients (Cheung, Lillie, Engel, Mendoza, & Sieber, 2007; Newsome, Sieber, Lillie, & Smith, 2010; Lillie, Sieber, Newsome, & Engel, 2009). Self-management, and ultimately clinical disease outcomes, should improve if such tools are used more effectively to engage patients in ways that lead to increased self-management.

The primary goal of this research carried out by Jakicic, (2003) was to identify the most efficient lifestyle pattern for the prevention of type-2 diabetes in a population of pre-diabetic overweight or obese individuals. The project comprises two distinct lines of evidence, both embracing European and overseas countries: 1) A multicentre, clinical randomized intervention trial of 3 year duration with a total of 2500 pre-diabetic participants, including children and adolescents, adults and elderly 2) Large population studies using data from all age groups. Focus in both lines of evidence will be on diet (specifically protein and glycemic index) and intensity of physical activity, as well as their interaction with the lifestyle factors, habitual stress and sleeping pattern as well as behavioral, environmental, cultural, and socioeconomic variables. Type-2 diabetes accounts for about 90% of all cases of diabetes, primarily caused by the worldwide obesity epidemic.

Diabetes is a costly disease and according to WHO, the direct health care costs of diabetes range from 2.5% to 15% of annual national health care budgets. This worrying trend calls for action and a need for a variety of innovative approaches. The research aimed to be such an innovative attempt including all necessary disciplines and stakeholders, who can contribute to developing new ways for the prevention of this wide-spread life-style related disease. The strategic impact of the research concerns the massive problems associated with the global diabesity epidemic (obesity and type-2 diabetes) and
therefore includes partners from Europe (East, West, North and South) and Australia, New Zealand, and Canada.

The research was carried out by the diabetes prevention program research group in 2012. It was found by the research that in the past 10 years, the total indiscerned pr capita cots of intervention for diabetes has increase for lifestyle ($4601) than Metformin ($2300) or Placebo ($769). Type 2 diabetes is a growing, serious and costly public health problem. The disease is mainly due to an increase in lifestyle changes, particularly physical inactivity and excess weight and obesity treatments. Lifestyle-related risk factors in the development of the disease on the other hand provide the opportunity for preventive interventions. Until recently, reliable evidence of type 2 diabetes prevention feasibility and effectiveness has not been there. The intervention group received, in addition to the regular nutrition specialist (dietician or nutritionist), individualized guidance. They were also offered the opportunity to participate in the type resistance training sessions, and were advised to increase overall physical activity. Under the guidance aimed at weight loss (5% or more of their baseline body weight), fat (<30% of total energy) and saturated fat (<10% of total energy) the amount of restriction in the diet, as well as fiber intake (less than 15 g / 1000 kcal) and physical activity (at least 30 minutes / day) was increased.

Diabetes status was assessed annually by 2-hour oral glucose tolerance, which was repeated for confirmation of diagnosis. The difference between groups in the incidence of diabetes was analyzed for the first time an average of 3.2 years of follow-up time, and the intervention phase was terminated an average of 3.9 years of follow-up time. From then on, the participants were followed for an average annual study visits for 3 years. Enhanced intervention group showed significantly greater lifestyle goals. They lost on average 4.5 kg during the first year of the study, and the three years of the weight was on average 3.5 kg below the output level. Controls weight decreased by an average of 1.0 kg and 0.9 kg in three years. Also, cardiovascular disease risk factors improved more in the intervention group. An average of 3.2 years of follow-up period, the incidence of diabetes was reduced by the intervention group 58% lower than in control subjects. The incidence of diabetes was less likely, with achieved lifestyle goals achieved. Those individuals whose diet contained no more than moderate amount of fat but high in fiber, lost weight to a considerable extent. They also had the lowest risk of diabetes, even after the effect of the change of weight was taken into account. On average, the three-year follow-up monitoring of the risk of diabetes was still in the intervention group showed significantly lower than 36%.
Another research by involved the diabetes disease risk assessment methodology used in the development of material for the population of a random sample extracted from the FINRISK 1987 (forecast model development) and FINRISK 1992 (forecast model validation) cohort of the study. Basic research participants 35-64 years of age were followed for diabetes identified Institution drug reimbursement registry tool to 1997. In the 1987 cohort (n = 4435) were observed in 10 years, including 182 new cases of drug treated diabetes and the 1992 cohort (n = 4615), 67 cases in five years. Age, body mass index, waist circumference, blood pressure, medication use, history of high blood glucose, physical activity and fruit and vegetables were selected into the diabetes risk test. In the 1987 cohort, the test identified 78% of future diabetes cases (sensitivity of the test), and 77% of people with diabetes were found during follow-up (test specificity). The 1992 cohort performed equally well. The final risk test form was also brought into question the presence of a family history of diabetes, and the age category over 64 years of age. DPS survey of the participants in the entry-level test predicted the risk of diabetes onset only, indicating the intensive lifestyle guidance. Results of this research show that the enhanced lifestyle guidance is possible to obtain a long term beneficial changes in high-diabetes-risk groups in diet and exercise habits, body weight and cardiovascular disease risk factors. Healthy living, in turn, will reduce the risk of developing diabetes. Enhanced guidance should be available, particularly for high-risk groups. Such high-risk individuals that can be identified quickly.

Costs of Diabetes and Costs of Complications

Several estimates have been published about the economic burden imposed to the health system by this condition. In the most recent published report, Avila et al. estimated the total national expenditure on diabetes mellitus, cardiovascular disease and obesity in 2006 came to USD$ 2,869.6 million representing 7% of the national health expenditure and 0.4% of the Gross National Product (GNP). From this amount 73% was financed by the state and 27% by the private sector (Saha, Gerdtham, Johansson, 2010). A total of 40.7% of this estimate was allocated solely to diabetes mellitus. In addition to this estimation, which is based on expenditure rather than costs, many other cost estimates have been published in the last two decades. Most studies evaluated used modeling techniques to project clinical benefit and cost outcomes. Likewise, most therapies involved in evaluating incoming higher cost as compared to standard therapy (Lenfant, 2003).

According to the authors, the analysis should include impact assessments beyond isolated in HbA1c, which would be useful to differentiate innovative products. Medical care charges increase
significantly for every 1% increase above HbA1c of 7% (Gilmer TP, O’Connor PJ, et al. 1997) Also, it is important to note that it is possible to anticipate that most studies published showed the cost-effectiveness of the lifestyle treatment as compared to taking drugs and combination therapies generic fixed dose given increased market competitiveness of diabetes interventions.

**Direct Costs of Diabetes**

In a report published in 2006, the total cost for Diabetes Mellitus in the country was USD$1,164.8 million dollars. These estimates are higher than the ones reported by Arredondo et al. (2005) using different methodology, where the total direct and indirect cost amounted to USD$ 317,631,206. A recent update by this group found total costs for 2010 came to USD$ 343,226,541 reflecting an increase of approximately 8% in a 5-year period (Kim, Bursae, et al., 2009,131-135).

**Indirect Cost of Diabetes**

In 2005 indirect costs were estimated at USD$ 177,220,390 (at an exchange rate corresponding to January 2003). From these costs, a major part was the cost of permanently disabled patients (USD$166,693,502), followed by the cost of mortality (USD$ 8,010,360), and the cost of temporarily disabled patients (USD$ 2,516, 528). The main chronic complications of diabetes are nephropathy, cardiovascular disease, retinopathy, neuropathy and peripheral vascular disease. Total annualized average diabetes costs (without complications), is equivalent to $707 US DLLS (Delahanty, Meigs, et al., 2002,1992-1998). When complications appear, this cost increases by 75% when nephropathy is present, 13% for vascular complications, 3% for neuropathy and 8% for retinopathy.

**Cost of Standard Therapy**

<table>
<thead>
<tr>
<th>Study referenced</th>
<th>Primary Care Office Visit</th>
<th>Laboratory assessments</th>
<th>Medication (w/o insulin)</th>
<th>Medication (with insulin)</th>
<th>Hospital Visits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jakicic et al. (2003)</td>
<td>Visit to the hospital</td>
<td>Blood test</td>
<td>Control Group, Experimental Group</td>
<td>3 to 4 times per year</td>
<td></td>
</tr>
<tr>
<td>Cody et al., (2002)</td>
<td>Hospital Visit</td>
<td>Glycohemoglobin test</td>
<td>No Control group</td>
<td>Experimental group</td>
<td>5 times per year</td>
</tr>
<tr>
<td>Diabetes prevention</td>
<td>Hospital Visit</td>
<td>Urine and Blood test</td>
<td>Control Group</td>
<td>Experimental Group</td>
<td>3 year duration</td>
</tr>
</tbody>
</table>
Studies on the Effectiveness of Lifestyle Interventions

Type 2 diabetes is a serious concern which is related to many complications and an increased mortality. The worldwide prevalence is estimated to rise to 438 million in two decades, increasing the burden posed by this disease (Beck, Ward, et al., 1961,561-571). The benefits of this intervention can be
ensured long after the counseling is stopped. It is imperative for the health policy makers to have an insight into the aspects that impact the translation of evidence based practice programs into a real world. An improved understanding of the implementation of the program may reveal benefits for the intervention delivery. But, due to increasing evidence on the effectiveness of diabetes prevention in the routine healthcare, the intervention evaluation and implementation remains limited (Marcus, Niaura, et al., 1992, 60-66).

Evidence Supporting Lifestyle Interventions for Diabetes Prevention

A number of efficacy trials from China, Finland, U.S.A, India and Japan provide strong empirical support for lifestyle change programs in preventing T2DM among individuals with impaired glucose tolerance (IGT). Reduction in T2DM incidence ranged between 42-58% in these various trials, with generally good maintenance for up to 20 years (Hickey, Owen, et al., 1992, 347-351). Moreover, behavioral interventions have been shown to be more cost-effective than drug treatment, particularly when delivered via group-based intervention programs. A series of ensuing implementation trials conducted in different countries in recent years have now also demonstrated that the findings from efficacy trials can be replicated in ‘real world’ community settings with more feasible, acceptable and cost-effective delivery systems and with similar outcomes (Daile, Calugi, et al., 2009).

Transferability and Uptake in Resource Poor Settings Requiring Critical Evaluation

The majority of these efficacy and implementation trials except the Da-Qing study in China and the Indian Diabetes Prevention Program (IDPP) were developed and delivered in developed countries that are very different from rapidly developing countries in terms of their health systems, culture, traditions and lifestyle behaviors related to nutrition and diet. Most of these programs were also undertaken in countries, where there was quite a strong enabling environment of policy and other supports for the prevention and control of chronic non-communicable diseases (NCDs) aimed at increasing population awareness of lifestyle-related risks (The Diabetes Prevention Program Research Group, 2012). These programs have typically focused on weight loss, greater intake of fiber, reduced total and saturated fat and increase in daily physical activity. Most of these programs have also used behavior change approaches and techniques that have emphasized outcome expectations, self-efficacy, setting of individual goals and creation of specific action plans in order to achieve lifestyle change in key behaviors. However, the socio-behavioral approaches and models on which these strategies are based
have also been largely derived from health behavior theories and models that have been primarily
developed in Europe and the United States. Currently, there is little research concerning the factors that
influence the feasibility and adaptation of T2DM prevention programs to more resource constrained
countries, cultures and settings (The Diabetes Prevention Program Research Group, 2012).

Lifestyle Intervention as the New the Diabetes Prevention Program

A myriad of diabetes prevention programs modeled on the DPP are carried out worldwide to
fight against the diabetes pandemic (The Diabetes Prevention Program Research Group, 2012). These
programs are individualized for specific target populations and optimized for the best use of resources
and budgets. Even though most of the programs are translational projects sharing classic constructs
such as lifestyle intervention, diet modification and exercise, the reported efficacy of these programs
differed dramatically due to different program designs and evaluation methods (Hamman, Wing, et al.,
2006).

Weight Loss and Diabetes Management

Percentage change from participants’ starting weight is a widely used indicator to assess and
evaluate the efficacy of diabetes prevention programs (Ali, et al., 2012). The DPP proclaimed that
diabetes can be delayed or averted through systematic and intensive lifestyle intervention (Knowler et
al., 2007). A follow-up study concluded that intervention to reduce diabetes should primarily target
weight reduction (Hamman et al., 2006). However, even when weight is regained after the DPP, the risk
reduction for diabetes resulting from lifestyle intervention can persist for at least 10 years (Knowler et
al., 2009). There are many reasons why weight loss is prevailing in diabetes prevention programs as the
main outcome. First, weight loss is an easy and affordable parameter to be measured repeatedly across
the whole program. Second, weight loss is a predictable consequence of diet modification and exercise
which are the two most common constructs in diabetes prevention programs, and which generally
manifests dose-response relationship. Furthermore, limited by the nature of their study designs and
ethical issues, most diabetes prevention programs are not allowed to include a control group so that
they fail to measure the “real” risk reduction the reduced diabetes incidence, which is more common in
long-term cohort or experimental studies.

Overall, weight loss seems to be a rational alternative and has been adopted by many programs.
However, weight loss alone may not fully reflect the efficacy of diabetes prevention programs in terms
of improving prediabetes conditions and reducing the risk of developing type 2 diabetes and its complications. The Finnish Diabetes Prevention Study demonstrated that the risk of diabetes was reduced 58% through lifestyle intervention after a 3-year follow-up in spite of minimal weight loss. More important, the authors emphasized that exercising 4 hours per week reduced the risk of diabetes in participants without weight loss (Tuomilehto et al., 2001). Many research studies have confirmed that beneficial changes in type 2 diabetes incidence can be achieved independently of weight loss (Pan et al., 1997; Ramachandran et al., 2006). Furthermore, the accuracy and reliability of weight change is problematic. Loss of muscle and bone mass instead of fat loss are likely to happen due to unhealthy diet and exercise plans. Stress caused by dramatic lifestyle change without sufficient family support may also contribute to weight loss. Additionally, weight measurement can be affected by confounding factors such as food and fluid intake prior to the measurement. The majority of individuals who successfully completed an initial behavioral weight loss program maintained a weight below their initial level. Monthly brief personal contact provided modest benefit in sustaining weight loss (Svetkey LP, Stevens VJ, et al. 2008).

Summary

The main environmental factors that increase the risk of type 2 diabetes are excessive food intake and sedentary lifestyle, with consequent overweight and obesity. A full treatment of diabetes should include not only a special diet for the treatment of pathology and moderate physical exercise routine, but also a constant medical supervision. The future research will examine two improvements in using health information technology and the collaborative care model: have patients view the diabetes video immediately prior to a clinic visit, and support providers in engaging the patient in SDM during the clinic visit itself. There is a need to implement a system that invites patients to view this video a few days prior to an already scheduled clinic visit, thereby providing patients with a clear timeframe in which to view the video and hopefully increase viewing rates. Though many of these already scheduled visits may not be intended as ‘diabetes self-management’ visits, such proactive efforts on the part of the collaborative care team members may seize them as such opportunities (Franz, Bantle, et al., 2002). Such a model will likely increase patients’ sharing of their reactions to the video during the clinic visit. Similarly, it is important to inform providers immediately prior to a visit with a patient who has viewed a video that the patient has done so, and assess the actual discussions that ensue between patient and provider. Such information will help us better understand the role of SDM in promoting self-
management behaviors. Overall, actively engaging both patient and provider in the provision of care is better achieved through a collaborative care model that uses behavioral health professionals as health coaches in order to better leverage existing tools that are often currently available yet underutilized by physicians.
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