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Effect of Medical Nutrition Therapy on Outcomes of Patients with Pre-diabetes in a Rural Nebraska Primary Care Clinic: A Pilot Study

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EFFECT OF MEDICAL NUTRITION THERAPY ON OUTCOMES OF PATIENTS WITH PRE-DIABETES IN A RURAL NEBRASKA PRIMARY CARE CLINIC: A PILOT STUDY

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Objective: Describe the impact of Medical Nutrition Therapy on health parameters of newly diagnosed patients with pre-diabetes in a rural Nebraska primary care clinic.

Background: Lifestyle interventions, including weight loss, exercise and diet, have a significant impact on diabetes prevention. Medical Nutrition Therapy (MNT) provided by a Registered Dietitian Nutritionist (RDN) is an essential part of any intervention approach. Several visits with an RDN have shown effective results. However, multiple visits become prohibitive, especially in rural areas, due to inaccessibility and cost when not covered by insurance.

Methods: This 2010 retrospective study of electronic health records examined newly diagnosed pre-diabetes patients who received (n=20, mean age 61, 85% female) or did not receive MNT (NMNT) (n=22, mean age 63, 82% female) in a 12 month time period after diagnosis. Health parameters (weight, Body Mass Index (BMI), fasting blood glucose (FBG), Hemoglobin A1C (A1C), lipids, blood pressure) were collected at baseline and repeat measurements were recorded from health records as close to one-year post diagnosis as available. Data were analyzed using Chi Square and Mixed Procedure.

Results: After adjusting for medications, greater weight loss and BMI change were observed and expected to continue in those who received MNT, although the difference was not significant. ($P > 0.05$). The MNT group had a significant predicted decrease from baseline to time 2 in FBG (*P*=0.036), in A1C (*P*=0.05*)* and an increase of nearly 4 mg/dl (*P*=0.028) in HDL cholesterol (HDL-C). The NMNT group experienced approximately a 50 mg/dl decrease in triglyceride levels (*P*=0.05) but also had unexpected medication starts or dosage increases (*P*=0.01). Other lipid and blood pressure changes were not significant.

Conclusions: Patients with pre-diabetes receiving limited MNT provided by a RDN had positive changes in body weight and BMI, a lowering of FBG and A1C, and improved HDL-C after a year post diagnosis, and less medication starts or changes than patients without MNT.

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CHAPTER I

INTRODUCTION

As early as the 1920's, Dr. Elliott Joslin spoke not only of the need for treatment of diabetes but also prevention.[1] Today more than twenty six million adults in the United States have diabetes. Another 79 million, or a third of the adult population, are estimated to have pre-diabetes according to a 2011 Centers for Disease Control and Prevention report.[2] This mirrors the obesity and overweight percentage rates which have soared to 97 million adults, a 48% increase over the past decade.[3,4] Of even greater concern is that obesity rates in children and adolescents have more than tripled in the past 30 years affecting their risk of developing diabetes.[5,6]

A combination of genetic and lifestyle factors effect the development of type 2 diabetes. Insulin resistance increase and beta cell loss during pre-diabetes years significantly impact the body's insulin needs and alter normal physiology leading to progression of diabetes. Higher body weights are associated with an increase in all cause morbidity and mortality and it is a preventable contributor to diseases such as type 2 diabetes. Lifestyle changes can improve insulin resistance, help preserve beta cell function, and slow or halt the development of type 2 diabetes.[7] Diabetes has reached epidemic levels and is found in almost every population worldwide. With increasing obesity rates and lack of physical activity, type 2 diabetes has become one of the leading chronic diseases surpassing the prediction rates for diabetes from 20 years ago.[3] The growing diabetes epidemic has had a devastating impact on quality of life and overall health-care costs. The United Kingdom Prospective Diabetes Study (UKPDS) investigated the effect of intensive blood glucose control versus conventional treatment in patients with type 2 diabetes over approximately 10 years. Researchers demonstrated a direct relationship between the risk of diabetic complications and glycemia over time. Each 1% absolute reduction in mean Hemoglobin A1C (A1C) levels was associated with a 37% decrease in the risk of microvascular complications and a 21% reduction in the risk of any diabetes-related complication or death.[8] Diabetes is the leading cause of kidney failure, non-traumatic lower-limb amputations, blindness and heart attack and stroke in adults in the United States so any improvement in A1C levels is likely to reduce these risks.[2] The consequences of diabetes are significant so there is urgency in finding ways to slow or halt the development of the disease.

Pre-diabetes raises short-term absolute risk of type 2 diabetes five- to six fold.[16] Pre-diabetes is recognized in individuals whose glucose levels, although not meeting criteria for diabetes, are too high to be considered normal. Pre-diabetes is defined by the American Diabetes Association as an impaired fasting glucose (IFG) (fasting plasma glucose (FPG) levels 100 mg/dl to 125 mg/dL) or impaired glucose tolerance (IGT) (2-h values in the oral glucose tolerance test (OGTT) of 140 mg/dL to 199 mg/dL). (Appendix 2) In 2010, statistics revealed that 10.9 million adults aged 65 or older had diabetes.[1] Type 2 diabetes (Appendix 3), once called adult-onset diabetes, was considered a disease of later life. Though it is more prevalent in age 65 and older, type 2 diabetes is now affecting people of all ages in staggering numbers. Evidence shows that those with pre-diabetes are likely to develop type 2 diabetes within 10 years unless steps are taken to prevent or delay it.[9] The Diabetes Prevention Program (DPP) provided conclusive evidence that lifestyle intervention in overweight persons with pre-diabetes can delay or prevent the progression to type 2 diabetes. Even a modest weight loss through dietary changes and increased physical activity had a significant impact on their chances of developing diabetes. Lifestyle interventions included diet and exercise changes through counseling and behavior modification. Poor nutrition appears to be a major contributor to this problem and medical nutrition therapy (MNT) for people with pre-diabetes appears to be one of the best approaches to prevention. MNT provided by a registered dietitian nutritionist (RDN) has been proven to be an important aspect of treatment in delaying or preventing the onset of diabetes.

Results from large randomized controlled trials (RCT) reported positive outcomes when subjects received numerous sessions with a RDN over an extended period of time. However, little is known about the impact of a limited number of MNT visits on outcomes in individuals with pre-diabetes. Patients in rural areas may have few resources and limited accessibility to diabetes programs and/or a RDN. MNT for pre-diabetes is typically not a covered service by health insurance, Medicare and Medicaid. Costs, travel, or knowledge of available resources may also be problems. Because of these issues, patients who choose to address their health issues often see a RDN for only one MNT visit. Patients lacking follow-up MNT support can have diminished outcomes over time, however, based on research findings.

CHAPTER II

LITERATURE REVIEW

Factors in the development of type 2 diabetes

Genetics- The development of diabetes is clearly linked to a family history of diabetes. The genetic components of insulin resistance and impaired insulin secretion, along with aging, involve multiple genes that are impacted more or less by environmental factors that trigger changes. Insulin resistance begins long before the onset of diabetes and is the underlying condition of insufficient insulin action at the cells receptor sites in response to elevated glucose levels. Pancreatic beta cell function is also found to be about 50% of normal at diagnosis of type 2 diabetes with changes beginning as soon as approximately 10 years earlier. Glucolipotoxicity and inflammatory mediators are factors that affect insulin secretion and impair insulin signaling. High triglycerides, depressed high density lipoprotein cholesterol (HDL-C), elevated blood pressure (BP), elevated fasting blood glucose (FBG) and abdominal obesity are all signs of insulin resistance or, metabolic syndrome, (Appendix 4) which often surface in pre-diabetes years. Impaired insulin secretion also occurs early leading to postprandial hyperglycemia and progresses due to pancreatic beta cell loss over time. With sufficient beta cell loss, diabetes develops. Aging is also associated with insulin resistance due to changes in body composition, namely body fat accumulation in the abdominal region and accompanying muscle mass loss.[10] Thus, the development of insulin resistance and type 2 diabetes is multifactorial. However, insulin sensitivity can be impacted by diet, weight loss, exercise or a combination of lifestyle changes that lead to an improvement in insulin response and blood glucose levels.

Diet- The wide spread epidemic of diabetes appears to be linked to changes in dietary patterns and poor nutritional intake across the globe. A study conducted at the India Institute of Diabetes at Mumbai identified nutritional problems in their culture that has accelerated the rate of conversion of pre-diabetes states to diabetes. They concluded that diets high in fat, and insufficient in healthy fatty acids, Vitamin D and antioxidants are the main problems and correlate this with a highly refined, processed, and preservative filled diet.[11] It is known that a diet high in fat, independent of body weight, has an impact on insulin sensitivity. However, the type of fat also matters. Epidemiological studies results found an association between higher fasting insulin and glucose levels and more pronounced glucose intolerance with a high saturated fat diet. Findings from long-term clinical trials support a diet that is rich in whole grains, fruits and vegetables, and other high fiber carbohydrates. Low-fat dairy products, moderate alcohol consumption, and reasonable coffee or tea intake may be part of a beneficial diet plan. Overall a diet that is low in total fat (<30% of energy), especially animal fat and saturated fat, and simple sugars appear to be best in prevention of diabetes.[12] A Mediterranean-style diet with foods of low-glycemic load may also affect the metabolic changes that occur with insulin resistance and the metabolic syndrome.[13] A recent review of prospective cohort studies showed consistent and significant lowering in the incidence of type 2 diabetes in individuals who consumed a lower-glycemic load diet.[14] Kahleova and colleagues found that a calorie-restricted vegetarian diet improved insulin sensitivity compared to a conventional diet over a 6 month period. They concluded that the effects might in part be explained by weight loss, especially visceral fat loss, which improved insulin sensitivity.[15] Weight loss through dietary calorie restriction and nutrient intake change are supported in several studies as a way of preventing diabetes.

Obesity- The association of obesity (Appendix 5 and 6) with increased risk of developing insulin resistance and type 2 diabetes is shown in many studies. Insulin resistance worsens in obesity due to metabolic changes and release of hormones, adipocytokines, non-esterified free fatty acids, and other substances from fat cells. Pancreatic beta cells increase insulin production to normalize glucose levels, but eventually due to beta cell loss glucose levels remain elevated. Researchers have shown that the development of type 2 diabetes can be delayed or possibly prevented in obese individuals if weight loss is achieved.[16] Jazet and colleagues showed that a loss of 50% of excess weight normalized endogenous glucose production and improved insulin sensitivity. The preservation of beta cells in the pancreas and the capacity to secrete adequate amounts of insulin was shown to be important in predicting outcomes of diet on glucose lowering in obese patients.[17] A review of studies by Norris and colleagues looked at the effectiveness of weight-loss and weight-control interventions on adults with pre-diabetes in prevention of diabetes. They concluded that weight-loss strategies that incorporate dietary, physical activity, or behavioral interventions producing significant weight improvements resulted in a significant reduction in diabetes occurrence in people with pre-diabetes.[18]

Physical inactivity- The rise in obesity in recent decades is attributed in part to the decrease in physical activity. Both cross-sectional and longitudinal study researchers have found physical inactivity to be an independent predictor of type 2 diabetes. The more physically active subjects had lower incidence of diabetes. Populations who have migrated to westernized countries have an increased risk of type 2 diabetes due to adopting more sedentary lifestyles compared to natives of their country of origin.[19] Activity Guidelines for Americans were published by the US Department of Health and Human Services in 2008 to give direction for weekly activity goals. (Appendix 7)

Preventing diabetes

Lifestyle intervention studies - Achieving and maintaining a healthy weight through diet and physical activity are interventions used most often in diabetes prevention trials in individuals at high risk for developing diabetes. Yoon and colleagues completed a 2013 meta-analysis of randomized controlled trials. They determined there is substantial evidence that the development of type 2 diabetes can be prevented or delayed through lifestyle intervention in most high-risk individuals.[20] One of the earliest lifestyle intervention studies was done in Malmö, Sweden. Eriksson and Lindgärde took subjects with early-stage type 2 diabetes and IGT and prospectively studied long-term lifestyle intervention effect on development of type 2 diabetes. After 6 years they found that greater than 50% of subjects with IGT at baseline, who made dietary changes and increased their physical activity level, had normalized glucose tolerance. They also found that more than 50% of those with diabetes were in remission.[21] Their results were supported by large follow-up randomized controlled trials in the United States, Finland, China, Japan, and in native Asian Indians.[22-30] The Da Qing Impaired Glucose Tolerance (IGT) and Diabetes Study, the Finnish Diabetes Prevention Study (DPS) and the US Diabetes Prevention Program (DPP) findings confirmed lifestyle intervention makes a difference.[22-24, 27-30] The DPS and DPP were the first and the largest randomized controlled trials to date, respectively, to study the efficacy of an intensive diet-exercise program in preventing or delaying type 2 diabetes in individuals with IGT. The DPS lifestyle intervention provided individualized counseling focused on reducing weight and fat intake and increasing fiber intake and exercise. The DPP worked to achieve 5-7 % weight reduction from initial body weight through a healthy low-calorie, low-fat diet and some form of moderate physical activity for at least 150 minutes per week. All of these studies provided evidence that in obese subjects with impaired glucose tolerance, lifestyle changes had a significant impact in preventing diabetes through healthy diet, weight loss and physical activity. Other large population groups were studied in Japan and in Asian Indians, and smaller groups in Sweden and the Netherlands. Although the groups differed in some manner, the initial results were all similar. Lifestyle intervention had an effect on incidence of diabetes development.[25-26]

Physical activity and weight loss effect- Physical activity and weight loss have been shown to be effective in the prevention of diabetes. The improvement in Malmö subjects' glucose tolerance was correlated to weight reduction and increased physical fitness that contributed to decreased mortality in the treatment groups.[21] Conclusions of a four-year follow-up of DPP revealed that an increase in physical activity sustained weight loss and helped reduce risks for those who did not lose weight. They also identified improved lipid parameters, reduced hypertension and improved fasting glucose and glucose tolerance with lifestyle modification.[24] The Da Qing IGT and Diabetes Study found similar results after active interventions ended in Chinese subjects after 6 years. The diet intervention alone was associated with a 31% reduction in the risk of developing type 2 diabetes while the exercise intervention alone showed a 42% reduction similar to diet and exercise combined.[22] The male subjects in Japan studied by Kosaka and colleagues had repeated dietary and lifestyle instruction which led to a 67% reduction in risk of diabetes over 4 years compared to controls who were only advised initially to maintain a normal body mass index by diet and exercise. They concluded that diabetes incidence was positively correlated with body weight change.[25] This was supportive of follow-up analyses of the DPS and the DPP suggesting weight loss as the factor that reduced diabetes incidence. During a 16-year follow-up of 85,000 females in the Nurses' Health Study, excess body fat was identified as the single most important determinant of type 2 diabetes. The study supported weight control through diet and exercise as the most effective way to reduce risk of developing type 2 diabetes by as much as 83%.[31] A 2005 review by Norris and colleagues concluded that dietary, physical activity or behavioral interventions significantly affected the weight of persons with pre-diabetes. Although they found weight loss amounts to be statistically insignificant, studies demonstrated weight loss even at modest amounts led to improvements in A1C, blood pressure and triglycerides.[18] Their findings may be explained by Perreault and colleagues and the DPP Research Group who looked at regression from pre-diabetes to normal glucose regulation. They concluded normal glucose regulation is key to prevention of diabetes, and although aging can affect this process, normal glucose regulation may be attained through weight loss, healthy eating and exercise.[32]

Medication effect- Several studies compared lifestyle intervention to medication intervention in the prevention of diabetes. Progression of IGT to type 2 diabetes is high in native Asian Indians, so Ramachandran and colleagues tested whether the progression to diabetes in this population could be altered by lifestyle modification, medication intervention (metformin) or both. They found that both lifestyle modification and metformin significantly reduced the incidence of diabetes, but there was no further benefit when the two were combined.[26] The DPP also compared lifestyle intervention to medication intervention (metformin) and found that although both had positive effects on prevention of type 2 diabetes, the lifestyle intervention was more effective, especially in older adults.[24] Three medication intervention studies, The Xenical in the Prevention of Diabetes in Obese Subjects (XENDOS (orlistat)), The Troglitazone in Prevention of Diabetes (TRIPOD (troglitizone)), and The Study to Prevent Non-Insulin-Dependent Diabetes (STOP-NIDDM (acarbose)), all demonstrated reduced risk in the progression to diabetes, and the medications may become important adjuncts to lifestyle intervention in the future.[18]

Long-term effects of lifestyle change - Findings of the Finnish Diabetes Prevention Study (DPS) showed that even after individual lifestyle counseling had stopped, people at high risk of developing type 2 diabetes continued to sustain lifestyle change that reduced the incidence of diabetes. Similar results were found in the DPP groups with diet and exercise intervention reducing the incidence of type 2 diabetes by more than half compared to the control group.[23, 24] A 4 year follow-up of DPS by Lindström, et al, reported the impact of lifestyle change continued to have an impact on diabetes incidence.[27] The Da Qing results extended to 6 years and showed significant results continued.[22] At 12-years, the Malmö intervention group had the same mortality rate as normal glucose tolerant control subjects and half the mortality rate of impaired glucose tolerant control subjects. After 13 years, DPS participants had relative risk reduction of 38%[28] similar to findings in the Da Qing Diabetes Prevention Study over 20 years (43%)[29] and the DPP Outcomes Study over 10 years.[30] The Swedish study showed lifestyle intervention had a significant effect until the third follow-up year when the effect disappeared. Ultimately, all studies found lifestyle intervention impacted type 2 diabetes incidence but results had a diminished effect over time.[32]

Implementation of interventions and the role of the RDN. The American Diabetes Association's (ADA) 2013 Clinical Practice Recommendations state that "patients with IGT, IFG, or an A1C of 5.7-6.4% (Appendix 8) should be referred to an effective ongoing support program targeting weight loss of 7% of body weight and increasing physical activity to at least 150 minutes/week of moderate activity such as walking." The Prevention/Delay of Type 2 Diabetes section (ADA 2013) goes on to state, "follow-up counseling appears to be important for success." Their general recommendations are "individuals who have pre-diabetes or diabetes should receive individualized MNT as needed to achieve treatment goals, preferably provided by a registered dietitian familiar with the components of diabetes MNT."[33] Large RCT's support lifestyle intervention, that is provided for a limited time, as an approach that produces long-term benefits in reducing the risk of type 2 diabetes in high-risk individuals. Though these studies have shown the efficacy of lifestyle intervention, one question remains a challenge. How can the same interventions be implemented in primary healthcare settings and who should provide it? Multiple studies have been designed to translate the DPP approach into routine clinical settings. Sakane and colleagues attempted to implement lifestyle interventions through health checkups in communities and worksites with public health nurses and determined after 3 years that existing healthcare resources were beneficial in preventing diabetes in high-risk subjects. Subjects attended and learned with positive outcomes when information was provided in places that were in close proximity and convenient in their own medical clinic.[34] The Active Prevention in High-Risk Individuals of Diabetes Type 2 in and Around Eindhoven (APHRODITE) study utilized nurse practitioners in Dutch primary care clinics to provide lifestyle counseling with goals of ≥5% weight reduction if overweight; physical activity for at least 30 minutes 5 days weekly; intake of dietary fat <30% of total energy intake; intake of saturated fat <10% of total energy intake; and intake of dietary fiber of at least 3.4 g per mega joule. (14g per 1000 Kcal) Four one-hour group meetings with a dietitian were provided during the first 5 weeks of an 18-month study. The cost of intervention was concluded to be suitable for real-life settings but the effect was modest compared to usual care, which they attributed in part to health-care providers (HCP) not being able to convince patients of the importance of weight loss or weight maintenance.[35] The DE-PLAN Study reported similar results in the first community-based lifestyle intervention program in Greece. Once high risk participants were identified, they participated in a one-year intervention program meeting bi-monthly with a dietitian. They found that although weight loss was moderate (1.0 ± 4.7 kg), glucose levels improved. They concluded that the DPP and DPS intervention strategies, though effective, were not practical in most communities or primary care practices. They suggested that group sessions with a dietitian, at a work site or near participant's residencies, could be a practical and feasible approach to lifestyle intervention for people with pre-diabetes.[36] Other studies, including The Healthy Living Partnership to Prevent Diabetes by Katula and colleagues found they could make modifications to the original DPP guidelines configuring it to meet their community needs and have successful outcomes.[37] A meta-analysis conducted by Cardona-Morrell, and colleagues concluded that lifestyle interventions for high-risk individuals are feasible when delivered by healthcare providers in regular clinical settings but show limitations in clinical benefit one year after the intervention concludes.[38] Concern was also raised by Yoon and colleagues in a recent review of the literature as to whether the interventions from evidenced-based trials could be replicated in community settings. Further studies, such as The Good Aging in Lahti Region (GOAL) Lifestyle Implementation Trial was designed to test the effectiveness of risk reduction objectives derived from the DPS in primary health care settings. Their goal was to determine if comparable results of the prevention trials could be achieved in real world conditions in the existing health-care system. Although subjects achieved dietary fiber and fat goals, only 12% of participants met weight loss goals of at least 5%. Public health nurses and physiotherapists conducted the groups, but the authors attributed the favorable nutrition outcomes to investment in a program dietitian. They also concluded that group-based lifestyle counseling is feasible in real-life settings for evidence-based diabetes prevention.[39]

Does a nutrition professional providing medical nutrition therapy affect outcomes? Wolf and colleagues conducted a one year randomized controlled trial with obese women with Type 2 diabetes. The intervention group received individual and group education and support from registered dietitians while the control group was provided with educational materials only. They found that the RDs' intervention group had significantly greater weight loss, waist circumference change and improved health outcomes. There was also an improvement in A1C level and decreased use of diabetes prescription medications compared to control group participants.[40] Kramer and colleagues studied the effect of a community-based diabetes prevention program delivered by diabetes educators (registered dietitians and nurses). Mean overall weight loss for participants was greater than 5% with significant decreases also noted in fasting plasma glucose, low-density lipoprotein cholesterol, triglycerides, and blood pressure after a 12 session DPP- modeled group program. The results were similar to other DPP translation efforts.[41] Multiple clinical trials and outcome studies have reported decreases in A1C with MNT intervention, including a registered dietitian-led diabetes management program in primary care clinics in Taiwan. Huang and colleagues concluded that on-site registered dietitians significantly improved the glycemic control of type 2 diabetic patients.[42] Sustained A1C improvements were also found at one year by Johnson and Thomas. A registered dietitian provided MNT to adult patients who had a 20% reduction in their A1C level compared to 2% reduction in subjects who had not received MNT intervention.[43] In 2002, Pastors and colleagues concluded that evidence-based research strongly suggested that MNT provided by a registered dietitian who is experienced in the management of diabetes is clinically effective and that MNT does make a difference.[44] Recently, Delahanty studied the role of registered dietitians in improving diabetes-related health outcomes in important landmark lifestyle intervention studies. She determined that the evidence clearly demonstrated RDs have an increasingly important role, serving also as a lifestyle coach and case manager, regarding early MNT intervention in obesity, pre-diabetes and diabetes. She found that RDs played a key role in the DDP findings where lifestyle intervention was more effective than medication in the prevention of type

2 diabetes. She also concluded that building long-term relationships with clients help sustain lifestyle habits that translate into health benefits and cost savings over time.[45]

Cost savings interventions- As the number of people with diabetes grows so does the costs associated with the disease. Using 2007 U.S. Census and Federal epidemiologic data, researchers Dall and Zhang and colleagues estimated that the average cost of national medical care for those with pre-diabetes was $25 billion.[46-47] While the impact of pre-diabetes costs is significant, an even greater concern is the cost associated with Type 2 diabetes exceeding an estimated $192 billion.[2] The American Diabetes Association's Standards of Medical Care in Diabetes-2013 recommend, "Because MNT can result in cost-savings and improved outcomes, MNT should be adequately covered by insurance and other payers."[33] A study conducted by Francis and colleagues compared healthcare utilization and costs of patients with or without hypertension and pre-diabetes. Of the patients that met study criteria, approximately a third progressed to diabetes within the data collection time. They concluded that over a 3-year follow-up, those with pre-diabetes who progressed to type 2 diabetes, had significantly higher healthcare utilization and overall costs increased by almost $1500 in 1 year compared with patients who did not progress to diabetes.[48]

Attention has shifted to primary prevention of type 2 diabetes because of the escalating costs associated with diabetes treatment. But is the cost of prevention through lifestyle intervention more reasonable? Eddy and colleagues, using a validated model, evaluated the cost effectiveness of the DPP. The results of analysis revealed that over 30 years there was an 11% reduction of high-risk persons getting diabetes after the DPP lifestyle program. Cost was estimated at $143,000 for lifetime, approximately a third less than starting intervention at diabetes diagnosis. They concluded that lifestyle modification should be recommended to all high-risk people to reduce the morbidity and mortality of diabetes. However, they also determined that the DPP program might be too expensive for implementation on a comprehensive basis.[49] Because researchers in Canada also recognized diabetes interventions could be expensive, they compared the cost and health outcomes of an intensive lifestyle modification program, metformin or no intervention to prevent progression to diabetes in IGT individuals. Their results suggested that although intensive lifestyle modification strategies were not the cheapest intervention in the treatment of pre-diabetes, the greatest health benefits were realized at reasonable costs and may generate savings over time.[50]

Registered dietitian nutritionist involvement in lifestyle intervention strategies is important and has been proven to be cost effective. The cost savings of the Improving Control with Activity and Nutrition (ICAN) program supported incorporating lifestyle interventions led by a registered dietitian. The savings for ICAN participants were significant in inpatient admissions and also suggested possible savings in obese type 2 diabetes patients where complications often require expensive treatments.[51] Franz and colleagues also looked at the cost and overall effectiveness of medical nutrition therapy provided by registered dietitian. They concluded that substantial metabolic control could be achieved through nutrition intervention using practice guidelines with a reasonable cost.[52] Sikand and colleagues confirmed that MNT could be a cost effective intervention. Dietitian intervention of an average of 3 one-hour sessions over 8 weeks led to not only improved clinical parameters, but also a realized cost savings of $3.03 in medication savings (statins) for every dollar spent on MNT. They cited statistically significant reductions in hospital admissions and physician office visits for patients with diabetes and cardiovascular disease that have received MNT.[53] However, despite the evidence, Medicare continues to deny payment for physician-referred MNT for pre-diabetes or cardiovascular disease. The chief medical officer of Blue Cross & Blue Shield of North Carolina, and other well-respected professionals recently published a peer-reviewed article on the value of MNT in weight management. They retrospectively evaluated the cost of and health benefits attributed to MNT for overweight or obese adult managed care members who participated in a weight management program. They found that individuals who received MNT were about twice as likely as matched controls to achieve a clinically significant reduction in weight and cost $0.03 per member per month.[54]

If lifestyle interventions remain successful over time, significant cost savings and improved health outcomes could be achieved. Many organizations, agencies, groups and individuals are working on ways to prevent diabetes. National efforts along with state and local programs are trying to address the epidemic through lifestyle intervention programming. The federal government, through the Centers for Disease Control and Prevention (CDC), allocates funding for state program development. In 2010, Congress passed legislation addressing diabetes prevention through H.R. 3590- the Patient Protection and Affordable Care Act, SEC. 399V-3- National Diabetes Prevention Program. The National Diabetes Prevention Program is based on the National Institutes of Health (NIH) research study and is to establish intervention programs for those at high risk of developing type 2 diabetes. The program emphasizes improving dietary choices, increasing physical activity, improving coping skills, and providing group support to help participants lose 5% to 7% of their body weight and get at least 150 minutes of moderate physical activity a week. Thirty-six states in the United States currently have initiated these programs. There are seven programs available in Nebraska at this time.[55]

The idea of disease prevention is not new. History tells us that about 400 BC Hippocrates included the concept of prevention in the Hippocratic Oath " I will prevent disease whenever I can, for prevention is preferable to cure". Now over 2400 years later we are still searching for answers on how to prevent disease. All of the evidence points to lifestyle modification, including MNT, as a cost-effective approach to type 2 diabetes prevention.[56] How we accomplish this in different types of clinical or community settings is yet to determined.

While lifestyle intervention programs in large urban healthcare systems have proven to be effective in halting or slowing the development of type 2 diabetes, little is known about how to translate these interventions into practice in rural primary care clinics where there can be more barriers to health care. Access to programs with registered dietitian nutritionists and exercise specialists, the professionals qualified to assist pre-diabetes clients with diet and exercise interventions, is limited in many rural areas of Nebraska. Distance, time, cost, and the lack of recognized value of MNT may be factors that impact whether patients receive limited or no MNT intervention for pre-diabetes.

A notation of change is the American Dietetic Association is now the Academy of Nutrition and Dietetics and registered dietitians may be referred to as registered dietitian nutritionists since publication of many of the referenced studies. This research study will measure the impact of a limited number of MNT sessions provided by a RDN on one-year outcomes of patients' with pre-diabetes in a rural primary care clinic in Nebraska.

The objectives are to: 1) retrospectively collect data from electronic health records (EHR) of patients newly diagnosed with pre-diabetes in 2010 receiving or not receiving MNT by a registered dietitian nutritionist in a one year period, 2) examine the data to determine if a difference is found within or between clinical outcomes of patients receiving or not receiving MNT, 3) determine if the outcomes are clinically relevant, 4) describe factors that may impact outcomes, 5) discuss research needed in the future.

CHAPTER III

METHODOLOGY

Study Design

A quasi-experimental research design was used in this retrospective study to describe the effect of medical nutrition therapy on patient's outcomes in a rural Nebraska primary practice clinic. Electronic health records were reviewed to identify patients diagnosed with pre-diabetes who were seen for medical care in the clinic in 2010. Subjects were identified through a computerized search using ICD 9 code 790.29 (abnormal glucose, abnormal non-fasting glucose, hyperglycemia, pre-diabetes) for all patients seen in the clinic from January to December 2010 by their health-care provider (HCP). Patients met diagnostic criteria if they had screening fasting plasma glucose of 100-125mg/dl (American Diabetes Association Categories of increased risk for diabetes (pre-diabetes)). Subjects were assigned to two groups for analysis; those who were referred by their HCP and received Medical Nutrition Therapy (MNT) (n=20) and those who did not receive MNT (NMNT) (no MNT referral or MNT referral but the patient did not seek MNT) (n=22). Deceased patients, pregnant women, those under 18 years of age, anyone seen for MNT in the past, records with missing diagnostic data, a diagnosis of abnormal glucose/pre-diabetes but did not meet the American Diabetes Association diagnostic criteria, and those who had developed type 2 diabetes or were not newly diagnosed with abnormal glucose/pre-diabetes during 2010 were excluded from the study.

MNT was individualized as needed by the RDN to achieve treatment goals using components of the Academy of Nutrition and Dietetics (AND) MNT Evidence-Based Nutrition Practice Guidelines for Type 1 and Type 2 Diabetes when counseling patients. All MNT subjects were advised to alter dietary intake and increase physical activity (approximately 150 min/week) to achieve a negative energy balance with the goal of 1 pound of weight loss weekly. Sessions included verbal instruction, review of materials, counseling for behavior modification, motivational interviewing, and goal setting lasting approximately 1 hour. Exercise recommendations were based on AND guidelines and the 2008 Physical Activity Guidelines for Adult Americans. A referral to an exercise specialist was made, as needed.

Data Collection

Baseline weight, height, BMI, FBG, cholesterol, HDL-C, low density lipoprotein cholesterol (LDL-C), triglycerides, and systolic and diastolic blood pressure at diagnosis and repeat measurements approximately 12 months from diagnosis as available were recorded. Also noted were referral from a HCP, any gastrointestinal disturbances (i.e. GERD, irritable bowel, or Celiac disease), and new medication starts or increased dosages for hypertension or hyperlipidemia during the year following diagnosis of pre-diabetes.

Institutional Review Board approval was obtained for the research project from the University of Nebraska-Lincoln. (Appendix 1) Patient information was kept confidential by removing names from the database and no other personally identifiable information was recorded. Approval was also obtained from the primary care clinic administrator.

Statistical analysis

Descriptive statistics were used to analyze demographic and clinical information. Due to the retrospective nature of the study, all data collection points were different depending on when the patient returned to the clinic for follow up visits after the initial diagnosis. Due to missing data, actual numbers varied throughout the analysis. Mixed model analysis was used to adjust for the pattern of variance and covariance and to account for individual random effects over time. Due to the limited number of time points (i.e., two times), the compound symmetry variance structure was used. This analysis was used to examine if condition (MNT/NMNT), time, their interaction, and medications started or increased can predict the outcomes of interest (i.e., FBG, A1C…). Chi Square was used to compare observed and expected medicine starts between MNT and NMNT groups. An alpha level of 0.05 was used to determine statistical significance, although any trending was considered clinically relevant. Data was analyzed with SAS statistical software 9.2, 2008.

CHAPTER IV

RESULTS

Characteristics of the 42 patients meeting criteria for the study are present in Table 1. Approximately half were seen for MNT by a Registered Dietitian Nutritionist (RDN) / Certified Diabetes Educator (CDE) for the first time after being newly diagnosed. The two groups were similar in number (n=22, n= 20), gender mix (female n=35, 82%, 85%), average age of 62 years old (63 and 61, respectively), and non-Hispanic white. Of the patients with available BMI data, a normal BMI (18.5-24.9) was found in 6% of MNT and 19% of NMNT patients at diagnosis. These patients met obesity criteria, a BMI greater than 30, in 61% of MNT patients and 44% of NMNT patients. (Table 6)

Baseline and 1-year clinical data means and standard deviations are shown in Table 2. There were no significant differences between groups at the initial comparison other than more subjects were women than men. Results of clinical outcomes after a year showed weight, BMI, FBG, A1C, total cholesterol and triglyceride decreased and HDL-C increased in both NMNT and MNT groups. Systolic blood pressure remained stable in the NMNT group, but decreased in the MNT group. Diastolic blood pressure increased in both groups. LDL-C decreased in the NMNT group but was stable in the MNT group. Although clinical changes occurred between the groups none of the changes reached statistical significance (Table 4) but change was still considered clinically relevant. Table 3 shows the change within each group from baseline to time 2, approximately one year later, with corrections for medication starts or increases and estimations of standard error. Data analysis showed that both the MNT and NMNT group lost weight. However, more weight was lost by the MNT group when medication starts or increases were considered. BMI decreases in the MNT group were double that of the NMNT group trending toward but not reaching statistical significance. (*P*=0.12) The MNT group started with a higher BMI but weighed approximately 12 pounds less than the NMNT group at diagnosis reflecting taller patients in the NMNT group. The MNT group had a significantly lower FBG level at approximately 1 year when corrected for medication changes (*P*=0.036). When no correction was made for medication, the significance was even greater (*P*=0.025). FBG levels were predicted to decrease in both groups. However, the MNT group was predicted to have an initial FBG 2.28 mg/dL higher than the NMNT group and was also expected to decrease an additional 4.71mg/dL beyond the NMNT group. The A1C decrease of 0.22 % points predicted in the MNT group was also significant (*P*=0.05) mirroring the decline identified in FBG levels of nearly 7mg/dL (*P*=0.036). The MNT group also had significant increases predicted in HDL-C levels of about 4 mg/dL (*P*=0.028) while the NMNT group had predicted decreases in triglycerides of 47 mg/dL (*P*=0.05). The difference between the NMNT and MNT groups at baseline and after one year are shown in Table 4. The biggest differences between the groups were in the parameters with the most significant change within the groups. The level of change varied with each parameter, however, there were no statistically significant differences identified between the NMNT and MNT groups for any parameter after one year.

New prescriptions for patients needing treatment for hypertension or hyperlipidemia during the year following diagnosis of pre-diabetes are shown in table 5.

Analysis revealed that the NMNT group had significantly more medication increases or starts than expected (*P*=0.01) compared to the MNT group.

HCP referrals for MNT were made in 79% of newly diagnosed cases of pre-diabetes in 2010. All patients in the MNT group had a HCP referral, as did approximately 55% of the NMNT group. If a referral was made for MNT, it was at the patient's discretion to set up the appointment, which happened 48% of the time. Of the patients seen for MNT, 80% were seen for one visit. Only one person was seen for more than 2 sessions. Patients were seen for an average of 1.2 visits during the year following diagnosis with a MNT session length of approximately 60 minutes.

Gastrointestinal disorders including irritable bowel syndrome, Celiac disease, chronic constipation and/or diarrhea and gastroesophageal reflux disease (GERD) were recorded in 9 (45%) MNT subjects and 12 (55%) NMNT subjects with pre-diabetes.

CHAPTER V

DISCUSSION

Diabetes is a chronic disease of differing types marked by elevated blood glucose levels resulting from increased insulin resistance, impaired insulin secretion, or both. Researchers now recognize that the pancreatic beta cell mass decreases over time leading to progressive development of the disease. Environmental and genetic factors affect the onset of type 2 diabetes and can be influenced by lifestyle choices.[7] MNT patients were newly diagnosed by their HCP in 2010, but when insulin resistance began and what degree of beta cell loss had already occurred is unknown. The initial mean FBG was higher in the MNT group. This may be due to a later diagnosis or longer duration of abnormal glucose levels than in the NMNT group, but there was no statistically significant difference found at baseline between the two groups.

Diabetes is an illness that requires monitoring, ongoing patient education and support in self-care management of the disease by health-care professionals to help reduce serious complications and premature death. [2] Registered dietitian nutritionists (RDN) familiar with components of diabetes MNT play an integral role in intervention strategies aimed at helping patients prevent the development of diabetes. Individual sessions with an RDN, as observed in this study, improved patients' health parameters that can diminish long-term complications and help prevent the progression to type 2 diabetes. The goal of MNT intervention is not only to control glucose levels but also to prevent the onset of vascular disease that can be expensive and life threatening. RDNs providing MNT help patients improve outcomes by normalizing blood pressure and lipid levels through diet and exercise. (Appendix 9 and 10) A concern for rural areas is limited exercise options often exist, especially in inclement weather, which can impact outcomes. The MNT patients significantly improved their HDL-C; possibly finding ways to maintain diet and exercise changes over a years' period of time. The NMNT group had a significant reduction in triglycerides, but they also had a significant increase in medication dosages or starts. These medications would be expected to lower elevated lipid or blood pressure levels, so additions or increases in medication could explain the significant improvements seen in triglyceride levels of NMNT subjects.

It is unknown why the NMNT group had significantly more medication starts or increase dosages than the MNT group. Wolf and colleagues concluded in their research that nutrition intervention by a RDN not only resulted in greater weight loss, better A1C levels and improved health outcomes, but they also had decreased use of diabetes prescription medications compared to control groups.[40] Sikand and colleagues also confirmed that 3 hours of RDN intervention over several weeks realized a medication cost savings for every dollar spent on MNT.[53] Because the MNT group had statistically fewer medication starts or dosage increases, medication side effects and costs would also be less for this group. If MNT patients followed RDN advice and started regular exercise, lost weight, and ate healthier it could be expected that need for medications would decrease or be limited due to improvements in lifestyle.

Preventing negative health outcomes in adults with diabetes can be difficult, as almost a third do not know they have it. For the same reason it is a bigger challenge to prevent diabetes in the estimated seventy-nine million adults with pre-diabetes who typically have no symptoms, no awareness of the disease process or understanding of how lifestyle can impact their outcomes. Local, state and national organizations are working to reduce incidence of diabetes by promoting healthy eating, regular exercise, and a healthy weight to people at high risk of developing diabetes. The HCPs (physicians and physician assistants) in this rural Nebraska primary care study referred patients to be seen by the RDN/CDE for MNT with positive outcomes at one year. Multiple visits with an RDN were proven successful in improving outcomes in large trials such as the DPP and DPS. In this study most subjects received only one MNT session over a one-year period. Current research points to the diminished effect limited visits have on outcomes over time. Large RCT studies used urban organizations with integrated multi-disciplinary intervention programs. Implementation and outcomes in smaller facilities or communities using American Diabetes Association intervention strategies are now being studied. There are benefits and concerns that are unique to rural areas, but even in small clinics, RDNs can provide services that help patients improve health outcomes. The average patient age in the study was 60 or older where DDP findings show lifestyle intervention to have the greatest benefit. Researchers confirm that as we age there is a greater risk for developing diabetes. Aging is also associated with an increase in body mass and fat deposition. Insulin resistance, a key underlying factor in abnormal glucose tolerance, is present in individuals who are obese, those with diabetes, and may worsen with age. Evidence tends to support an association between abdominal obesity and insulin resistance. Why visceral obesity causes insulin resistance is not clear but may be related to release of insulin resistant factors from fat cells. It does appear, however, that insulin resistance is reversed quickly in response to negative energy balance long before there is reversal of obesity.[4] Several studies report that as body weight decreases, insulin sensitivity and glucose tolerance improve. Other longitudinal studies indicate regular aerobic exercise in middle-aged and older adults significantly improve glucose metabolism. A lower calorie intake and body weight reduction is proven to increase insulin sensitivity[3] Results of this study showed that little weight loss occurred or was maintained at approximately one year. Greater weight loss was observed in most patients closer to the time of intervention; however, this data was only observed, not collected and analyzed. Even though patients had modest weight loss (-2.6 lb.) and BMI change (-0.6) there were significant improvements in FBG, A1C, and HDL-C. Lifestyle interventions to promote healthy weight, a nutritious diet and exercise have been shown to improve insulin sensitivity and bring blood glucose, blood pressure, and lipids to near normal levels.[7] Norris and colleagues concluded that weight loss at modest amounts, even though not statistically significant, led to improvements in A1C, blood pressure and triglycerides.[18] Researchers from Greece found in the DE-PLAN study that although weight loss was moderate at about 2 pounds, glucose levels improved in subjects after a one-year intervention meeting bi-monthly with a RDN. The findings in this MNT intervention study revealed significant changes within the groups but not between the groups. Because of limited or no follow up in the MNT group, regression to near the NMNT group is predictable, as shown in other research findings. This may help explain why there is no difference seen between the groups. In addition, results may be similar at a year because of improvements in clinical parameters in the NMNT group after medication changes or additions. Because of uncontrolled variables, data and time points missing, correction of data was needed and then showed significant changes within the MNT group.

An interesting side note was that gastrointestinal (GI) disorders were documented in approximately 50% of the pre-diabetes patients. Why GI problems are disturbing half of the patients studied and if it affects outcomes in this population needs to be studied further.

Dietary intervention is recommended for individuals with pre-diabetes and should be provided by a registered dietitian nutritionist who is skilled in MNT for diabetes when possible. Studies show that multiple individual sessions with a RDN providing MNT helped patients work for a goal weight loss of at least 7% of initial body weight by addressing eating behaviors, improving nutritional intake by lowering fat and increasing fiber intake and developing an exercise plan. Individualized MNT assists patients in achieving treatment goals and has been shown to improve outcomes with cost savings. However, pre-diabetes is not a covered diagnosis by most third party payers even though associations such as the Academy of Nutrition and Dietetics and the American Diabetes Association recommend MNT be covered by insurance and other payers because of improved outcomes and cost savings. If a patient is willing or able to pay for services, diabetes programs and RDNs may not be easily accessible in rural areas due to distance, cost, and limited or no appointment hours for working people. The patients in this study all traveled within a 30-mile radius of the facility and paid for the visit expenses. These could have been limiting factors for some patients and might explain why some did not seek MNT after an HCP referral or return for follow up sessions. Pre-diabetes patients generally do not feel ill or have symptoms that affect their daily life. This may be another reason they do not seek RDN counseling or follow up. The bottom line is that patients are not getting MNT even though researchers support MNT provided by a RDN over several sessions as being highly effective in diabetes prevention. Highly motivated patients are more likely to participate in clinical trials and take their health-care providers advice in seeking MNT. Clinical studies show that patients are more likely to seek help with lifestyle intervention if encouraged by their HCP to do so. Why patients did not attend MNT sessions after a physician referral is unknown but further study may help in understanding patient concerns and aid in finding solutions to this problem. It is unknown why HCPs were not referring for MNT or not consistently documenting referrals for MNT in the EHR and is an area that could be investigated further. Although HCPs recognize the impact of diabetes on patients' health they may not be aware of what an RDN can do for their patients in preventing diabetes. Further studies on how HCPs view RDN skills and utilize them may be helpful in positioning RDNs for future roles in diabetes prevention.

Other questions that need answered concern RDNs accessibility to HCPs and patients, whether or not adequate positions or RDNs are available to provide the care, and if the RDN may not be perceived as the expert? Could awareness in the need for treatment of pre-diabetes by HCPs and the public be low? It is also unknown why patients in this study chose to receive MNT. They may have been motivated to make changes for many reasons. More MNT than NMNT subjects were obese which may have motivated them to seek help in making change. Several studies discuss motivation as a driving factor in lifestyle modification success. How we reach patients with the greatest need who are not motivated to change has yet to be discovered.

This study was limited by inconsistent or missing data within MNT and non-MNT groups due to retrospectively collected information. The small sample size impacted the ability to see significance or change that may have occurred so should be considered a pilot study. The population was predominately females, which tend to visit their HCP more regularly. Those who chose to complete the MNT referral may have been more motivated for change, been more affluent, had more flexibility in their schedule, been more highly educated, and possessed good problem solving skills. There were no minorities and the age of patients did not include children and young adults. Single MNT sessions for patients with pre-diabetes were common as patients were financially responsible for the visit. Because of low return visits this study was unable to compare the difference that might occur with multiple MNT sessions over time. MNT provided in an individual session is effective but MNT in a group medical visit format in rural settings should also be considered. Multiple MNT visits over time with a RDN leads to more significant outcomes for those with pre-diabetes. Although there is an initial investment in payments for MNT, cost savings and improved quality of life can be realized over time and should be researched further.

CHAPTER VI

CONCLUSIONS

The results of this study suggest that Medical Nutrition Therapy provided by a Registered Dietitian Nutritionist has a positive effect on clinical outcomes of newly diagnosed pre-diabetes patients. Despite the small study sample, clinically relevant changes were observed in BMI and weight among those who received MNT. Significantly fewer medications starts or increased dosages (P=0.01) were found in those receiving MNT and a significantly lower FBG (P=0.036) and A1C (P=0.05) along with improved HDL-C (P=0.03) were observed in patients at approximately one year with median of 1 visit.

In recent years, evidence from large RCTs have shown the impact of MNT intervention on delaying the onset of type 2 diabetes in high-risk groups. Most of the subjects, however, were seen in urban organizations with integrated multi-disciplinary intervention programs over many visits. Fewer resources for program implementation and delivery compared to experimental settings may influence results of any type of intervention in rural primary care. The reality for rural area patients is that nutrition intervention may not be easily accessible to them. Distance, time, travel, cost, RDN availability and provider referral may all impact whether a patient is seen for MNT. Lifestyle change is key to impacting pre-diabetes and this requires continued support, reassessment, problem solving and goal setting over time. Unfortunately, private insurance, Medicare and Medicaid do not pay for MNT for pre-diabetes and is likely a barrier to education and counseling.

While we need to prove our value and money saving impact through further randomized clinical controlled trials, registered dietitian nutritionists working in practice settings can use electronic health records now to conduct chart reviews to measure patient outcomes. This evidence is needed to support the effect MNT has on clinical outcomes in people with pre-diabetes. From this information can come changes needed in policy and reimbursement for MNT.

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APPENDICES

Table 1.
Baseline Characteristics of Study Population*

	Non MNT group (n=22)	MNT group (n=20)
Gender		
Female	18 (82%)	17 (85%)
Male	4 (18%)	3 (15%)
Age		
Year mean (range)	63 (41-83)	61 (43-86)
Weight, mean (SD**),** lbs.	202.2 (45.3)	189.7 (27.7)
Height (SD) in.**	67.3 (4.0)	65.3 (3.3)
Body Mass Index, mean (SD)**	30.8 (6.5)	31.6 (5.1)
Normal	3 (19%)	1 (6%)
Overweight	6 (38%)	6 (33%)
Obese	7 (44%)	11(61%)
Race		
Caucasian	22 (100%)	20 (100%)
Other	0	0
HCP Referral for MNT *		
Yes	13 (59%)	20 (100%)
No	9 (41%)	0

* No statistically significant differences between groups; ** Data missing; *** Health-care providers are physicians and physician assistants; MNT- Medical Nutrition Therapy; SD- Standard Deviation; BMI formula: weight (Kg)/Height (m^2)

Table 2.

Clinical Data of Non MNT and MNT Groups at Baseline and 1 Year

	NMNT Group		MNT Group	
Parameters	Initial Mean (SD)	After 1 year Mean (SD)*	Initial Mean (SD)	After 1 year Mean (SD)*
Weight (lbs.)	202.2(45.3)	193.8(40.9)	189.70(27.7)	187.3(26.6)
Body mass index **	30.8(6.5)	30.0(5.6)	31.6(5.2)	30.9(4.1)
Fasting blood glucose (mg/dl)	106.8(9.8)	103.7(13.1)	109.9(6.9)	102.7(12.1)
Hemoglobin A1C (%)	6.1(0.3)	6.0(0.4)	6.2(0.2)	5.8(0.3)
Blood pressure (mmHg)				
Systolic	126.5(15.5)	126.3(13.9)	125.9(17.4)	122.8(14.7)
Diastolic	76.2(11.2)	76.7(9.3)	71.4(12.1)	72.9(9.5)
Total cholesterol (mg/dl)	197.5(42.4)	185.8(45.8)	194.4(60.8)	196.7(78.4)
Lipoprotein cholesterol (mg/dl)				
Low density (LDL)	109.3(35.7)	105.5(40.0)	110.1(39.9)	110.6(53.1)
High density (HDL)	52.5(15.9)	54.3(16.7)	50.8(16.5)	51.9(21.6)
Triglycerides (mg/dl)	185.6(124.8)	129.8(56.1)	149.8(95.0)	130.4(86.0)

SD-Standard Deviation; * Data missing, last recorded value close to 12 months; **BMI formula: weight (Kg)/Height (m^2)

Table 3.

Clinical Changes Within Non MNT and MNT Groups After 1 Year

Parameter	**NMNT group** Difference at time 2 Mean (SE)	***P* Value**	**MNT group** Difference at time 2 Mean (SE)	***P* Value**
Weight (lbs.)	-2.45(2.67)	0.37	-2.61(2.49)	0.30
Body Mass Index*	-0.35(0.43)	0.42	-0.61(0.38)	0.12
Fasting blood glucose (mg/dl)	-2.07(2.82)	0.47	-6.78(3.11)	0.036**
Hemoglobin A1C (%)	-0.09(0.07)	0.27	-0.22(0.10)	0.05**
Blood pressure (mmHg)				
Systolic	-0.71 (3.92)	0.86	-2.95(3.99)	0.46
Diastolic	-0.26 (2.77)	0.93	0.68(2.82)	0.81
Total cholesterol (mg/dl)	-2.92(8.29)	0.73	-0.54(9.44)	0.96
Lipoprotein cholesterol (mg/dl)				
LDL	2.84(7.64)	0.71	1.91(9.44)	0.84
HDL	0.31(1.37)	0.83	3.90(1.65)	0.028**
Triglycerides (mg/dl)	-47.17 (22.88)	0.05**	-32.16(27.31)	0.25

* Data missing, last recorded value close to 12 months; **significant value; SE- Standard Error; BMI formula: weight (Kg)/Height (m^2)

Table 4.

Difference Between Non MNT and MNT Groups at Baseline and 1 Year

Parameter	Difference between NMNT and MNT groups Time 1 Mean (SE)	*P* Value	Time 2 Mean (SE)	*P* Value
Weight (lbs.)	-7.56(13.61)	0.58	-7.72(13.67)	0.58
Body Mass Index*	1.96(2.18)	0.37	1.71(2.18)	0.44
Fasting blood glucose (mg/dl)	2.28(3.67)	0.54	-2.43(4.12)	0.56
Hemoglobin A1C (%)	-0.04(0.15)	0.78	-0.17(0.15)	0.26
Blood pressure (mmHg)				
Systolic	3.53(5.31)	0.51	1.28(5.40)	0.81
Diastolic	-3.52(3.72)	0.35	-2.58(3.79)	0.50
Total cholesterol (mg/dl)	9.13 (20.28)	0.66	11.50 (20.81)	0.58
Lipoprotein cholesterol (mg/dl)				
LDL	20.55 (13.79)	0.14	19.63 (14.31)	0.18
HDL	1.90 (5.39)	0.73	5.47(5.46)	0.32
Triglycerides (mg/dl)	-44.73 (37.58)	0.24	-29.73 (39.98)	0.46

SE- Standard Error; * Data missing, last recorded value close to 12 months; BMI formula: weight (Kg)/Height (m^2)

Table 5.
Medication Starts or Increases in NMNT and MNT Groups After 1 Year

	NMNT group+	MNT group**	*P* value
Medication class			
Blood pressure (BP)	7	0	
Lipids	5	2	
No new medications for BP, lipids, or blood glucose	9	16	
Total starts/increased dose	12	2	**0.01***

*Due to small sample size chi square may not be valid; **Data missing; + 3 subjects had 2 or more medication changes or dosage increases; (N)MNT- (non) medical nutrition therapy; BP- blood pressure

Appendix 1. **Institutional Review Board Approval Letter**

University of Nebraska Lincoln

August 20, 2011

Charlene Dorcey
Department of Nutrition and Health Sciences
103 S Michigan Ave York, NE 68467

Nancy Lewis
Department of Nutrition and Health Sciences
316E LEV, UNL, 68583-0806

IRB Number: 20110811829EP
Project ID: 11829
Project Title: Does Medical Nutrition Therapy affect outcomes in patients with pre-diabetes?

Dear Charlene:

This letter is to officially notify you of the approval of your project by the Institutional Review Board (IRB) for the Protection of Human Subjects. It is the BoardÂ's opinion that you have provided adequate safeguards for the rights and welfare of the participants in this study based on the information provided. Your proposal is in compliance with this institutionÂ's Federal Wide Assurance 00002258 and the DHHS Regulations for the Protection of Human Subjects (45 CFR 46). Your project was approved as an Expedited protocol, category 5.

Date of EP Review: June 30, 2011

You are authorized to implement this study as of the Date of Final Approval: 08/20/2011. This approval is Valid Until: 08/19/2012.

We wish to remind you that the principal investigator is responsible for reporting to this Board any of the following events within 48 hours of the event:
* Any serious event (including on-site and off-site adverse events, injuries, side effects, deaths, or other problems) which in the opinion of the local investigator was unanticipated, involved risk to subjects or others, and was possibly related to the research procedures;
* Any serious accidental or unintentional change to the IRB-approved protocol that involves risk or has the potential to recur;
* Any publication in the literature, safety monitoring report, interim result or other finding that indicates an unexpected change to the risk/benefit ratio of the research;
* Any breach in confidentiality or compromise in data privacy related to the subject or others; or
* Any complaint of a subject that indicates an unanticipated risk or that cannot be resolved by the research staff.

For projects which continue beyond one year from the starting date, the IRB will request continuing review and update of the research project. Your study will be due for continuing review as indicated above. The investigator must also advise the Board when this study is finished or discontinued by completing the enclosed Protocol Final Report form and returning it to the Institutional Review Board.

If you have any questions, please contact the IRB office at 472-6965.

Sincerely,

William G. Thomas

William Thomas, Ph.D.
Chair for the IRB

Association for the Accreditation of Human Research Protection Programs, Inc.
Full Accreditation

Appendix 2. **American Diabetes Association Testing for Diabetes in Asymptomatic Patients - Categories of Increased Risk for Diabetes (Prediabetes) ***

FPG 100 mg/dL to 125 mg/dL (5.6 mmol/L to 6.9 mmol/L) (IFG)

OR

2-h plasma glucose in the 75-g OGTT 140 mg/dL to 199 mg/dL (7.8 mmol/L to 11.0 mmol/L) (IGT)

OR

A1C 5.7-6.4%

*For all three tests, risk is continuous, extending below the lower limit of the range and becoming disproportionately greater at higher ends of the range.

American Diabetes Association. Standards of Medical Care in Diabetes-2013. *Diabetes Care*. 2013;36(suppl 1): S13. Table 3.

Appendix 3. **American Diabetes Association Classification and Diagnosis of Diabetes Mellitus - Criteria for Diagnosis of Diabetes**

A1C ≥6.5%. The test should be performed in a laboratory using a method that is NGSP certified and standardized to the DCCT assay. *

OR

FPG ≥126 mg/dL (7.0 mmol/L). Fasting is defined as no caloric intake for at least 8 h. *

OR

2-h plasma glucose ≥200 mg/dL (11.1 mmol/L) during a OGTT. The test should be performed as described by the WHO, using a glucose load containing the equivalent of 75 g anhydrous glucose dissolved in water. *

OR

In a patient with classic symptoms of hyperglycemia or hyperglycemia crisis, a random plasma glucose ≥200 mg/dL (11.1 mmol/L).

American Diabetes Association. Standards of Medical Care in Diabetes-2013. *Diabetes Care*. 2013;36(suppl 1): S13. Table 2.

Appendix 4. **Diagnostic Criteria for Metabolic Syndrome**

Elevated Waist Circumference

- Men: >40 inches
- Women: >35 inches

Elevated Triglycerides (TG)

- ≥150 mg/dL
  or
- Drug treatment for elevated TG

Reduced HDL-C

- Men: <40 mg/dL
- Women: <50 mg/dL
  or
- Drug treatment for reduced HDL-C

Elevated Blood Pressure

- ≥130 mmHg Systolic BP
  or
- ≥85 mmHg Diastolic BP
  or
- Drug treatment for hypertension

Elevated Fasting Plasma Glucose

- ≥100 mg/dL
  or
- Drug treatment for elevated glucose

**Any 3 of 5 criteria constitute a diagnosis.

Alberti K, Eckel R, Grundy S, et al. Harmonizing the metabolic syndrome. A Joint Interim Statement of the International Diabetes Federation Task Force on Epidemiology and Prevention. National Heart, Lung and Blood Institute; American Heart Association; World Health Federation; International Atherosclerosis Society; and International Association for the Study of Obesity. *Circulation.* 2009; 120:1640-1645.

Appendix 5. **Classification of Overweight and Obesity by Body Mass Index**

Classification	**BMI**
Underweight	<18.5
Normal	18.5-24.9
Overweight	25.0-29.9
Obesity (Class I)	30.0-34.9
Obesity (Class II)	35.0-39.9
Extreme obesity (Class III)	≥40

National Heart, Lung, and Blood Institute. *Clinical Guidelines on the Identification, Evaluation and Treatment of Overweight and Obesity in Adults.* Bethesda, MD: National Institutes of Health; 1998.

Appendix 6. **Body Mass Index Table**

Body Mass Index Table

	Normal						Overweight					Obese										Extreme Obesity														
BMI	**19**	**20**	**21**	**22**	**23**	**24**	**25**	**26**	**27**	**28**	**29**	**30**	**31**	**32**	**33**	**34**	**35**	**36**	**37**	**38**	**39**	**40**	**41**	**42**	**43**	**44**	**45**	**46**	**47**	**48**	**49**	**50**	**51**	**52**	**53**	**54**
Height (inches)	**Body Weight (pounds)**																																			
58	91	96	100	105	110	115	119	124	129	134	138	143	148	153	158	162	167	172	177	181	186	191	196	201	205	210	215	220	224	229	234	239	244	248	253	258
59	94	99	104	109	114	119	124	128	133	138	143	148	153	158	163	168	173	178	183	188	193	198	203	208	212	217	222	227	232	237	242	247	252	257	262	267
60	97	102	107	112	118	123	128	133	138	143	148	153	158	163	168	174	179	184	189	194	199	204	209	215	220	225	230	235	240	245	250	255	261	266	271	276
61	100	106	111	116	122	127	132	137	143	148	153	158	164	169	174	180	185	190	195	201	206	211	217	222	227	232	238	243	248	254	259	264	269	275	280	285
62	104	109	115	120	126	131	136	142	147	153	158	164	169	175	180	186	191	196	202	207	213	218	224	229	235	240	246	251	256	262	267	273	278	284	289	295
63	107	113	118	124	130	135	141	146	152	158	163	169	175	180	186	191	197	203	208	214	220	225	231	237	242	248	254	259	265	270	278	282	287	293	299	304
64	110	116	122	128	134	140	145	151	157	163	169	174	180	186	192	197	204	209	215	221	227	232	238	244	250	256	262	267	273	279	285	291	296	302	308	314
65	114	120	126	132	138	144	150	156	162	168	174	180	186	192	198	204	210	216	222	228	234	240	246	252	258	264	270	276	282	288	294	300	306	312	318	324
66	118	124	130	136	142	148	155	161	167	173	179	186	192	198	204	210	216	223	229	235	241	247	253	260	266	272	278	284	291	297	303	309	315	322	328	334
67	121	127	134	140	146	153	159	166	172	178	185	191	198	204	211	217	223	230	236	242	249	255	261	268	274	280	287	293	299	306	312	319	325	331	338	344
68	125	131	138	144	151	158	164	171	177	184	190	197	203	210	216	223	230	236	243	249	256	262	269	276	282	289	295	302	308	315	322	328	335	341	348	354
69	128	135	142	149	155	162	169	176	182	189	196	203	209	216	223	230	236	243	250	257	263	270	277	284	291	297	304	311	318	324	331	338	345	351	358	365
70	132	139	146	153	160	167	174	181	188	195	202	209	216	222	229	236	243	250	257	264	271	278	285	292	299	306	313	320	327	334	341	348	355	362	369	376
71	136	143	150	157	165	172	179	186	193	200	208	215	222	229	236	243	250	257	265	272	279	286	293	301	308	315	322	329	338	343	351	358	365	372	379	386
72	140	147	154	162	169	177	184	191	199	206	213	221	228	235	242	250	258	265	272	279	287	294	302	309	316	324	331	338	346	353	361	368	375	383	390	397
73	144	151	159	166	174	182	189	197	204	212	219	227	235	242	250	257	265	272	280	288	295	302	310	318	325	333	340	348	355	363	371	378	386	393	401	408
74	148	155	163	171	179	186	194	202	210	218	225	233	241	249	256	264	272	280	287	295	303	311	319	326	334	342	350	358	365	373	381	389	396	404	412	420
75	152	160	168	176	184	192	200	208	216	224	232	240	248	256	264	272	279	287	295	303	311	319	327	335	343	351	359	367	375	383	391	399	407	415	423	431
76	156	164	172	180	189	197	205	213	221	230	238	246	254	263	271	279	287	295	304	312	320	328	336	344	353	361	369	377	385	394	402	410	418	426	435	443

Source: Adapted from *Clinical Guidelines on the Identification, Evaluation, and Treatment of Overweight and Obesity in Adults: The Evidence Report.*

Appendix 7. **2008 Physical Activity Guidelines for Adult Americans**

Adults (aged 18–64)

- 2 hours and 30 minutes a week of moderate-intensity physical activity

  or

- 1 hour and 15 minutes (75 minutes) a week of vigorous-intensity aerobic physical activity

  or

- An equivalent combination of moderate- and vigorous-intensity aerobic physical activity.
- Aerobic activity should be performed in episodes of at least 10 minutes, preferably spread throughout the week.

Additional health benefits are provided by increasing to

- 5 hours (300 minutes) a week of moderate-intensity aerobic physical activity

  or

- 2 hours and 30 minutes a week of vigorous-intensity physical activity

  or

- An equivalent combination of both.
- Also do muscle-strengthening activities that involve all major muscle groups performed on 2 or more days per week.

Older Adults (aged 65 and older)

- Older adults should follow the adult guidelines.
- If this is not possible due to limiting chronic conditions, older adults should be as physically active as their abilities allow.
- Older adults should avoid inactivity.
- Older adults should do exercises that maintain or improve balance if they are at risk of falling.

Adults with chronic conditions

- Seek the important health benefits from regular physical activity
- Physical activity only under the guidance of a health care provider.

US Department of Health and Human Services. 2008 Physical Activity Guidelines for Americans. http://www.health.gov/paguidelines. Accessed March 23, 2013.

Appendix 8. **Correlation of A1C with Mean Plasma Glucose**

A1C (%)	Mean Plasma Glucose (mg/dL)
6	126
7	154
8	183
9	212
10	240
11	269
12	298

American Diabetes Association. Standards of Medical Care in Diabetes-2013. *Diabetes Care*. 2013;36(suppl 1): S19. Table 8.

Appendix 9. **Classification of Blood Pressure in Adults**

Classification	Blood pressure, mmHg	Lifestyle Modification
Normal	SBP* <120 and DBP+ <80	Encourage
Prehypertension	SBP 120-139 or DBP 80-89	Yes
Stage 1 hypertension	SBP 140- 159 or DBP 90- 99	Yes
Stage 2 hypertension	SBP ≥160 or DBP ≥100	Yes

*Systolic blood pressure; +Diastolic blood pressure

The Seventh Report of the Joint National Committee on Prevention, Detection Evaluation and Treatment of High Blood Pressure: The JNC 7 Report. Bethesda, MD: National Institutes of Heart, Lung, and Blood Institute; 2003. NIH publication 03-5231.

Appendix 10. **Classification of Total, LDL, and HDL Cholesterol and Triglycerides**

LDL-C

- <70 mg/dL with or high risk for diabetes or overt CVD
- Optimal: <100 mg/dL
- Near or above optimal: 100-129 mg/dL
- Borderline high: 130-159 mg/dL
- High: 160-189 mg/dL
- Very high: ≥190 mg/dL

Total Cholesterol

- Desirable: <200 mg/dL
- Borderline high: 200-239 mg/dL
- High: ≥240 mg/dL

HDL-C

- Low: <40 mg/dL in men; <50 mg/dL in women
- High: ≥60 mg/dL

Triglycerides

- Normal: <150 mg/dL
- Borderline high: 150-199 mg/dL
- High: 200-499 mg/dL
- Very high: ≥500 mg/dL

Third Report of the Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Panel III). Bethesda, MD: National Institutes of Health, National Heart, Lung, and Blood Institute; 2001. NIH publication 01-3670.