The Effect of Medical Nutrition Therapy by a Registered Dietitian Nutritionist in Patients with Prediabetes Participating in a Randomized Controlled Clinical Research Trial

Anna R. Parker, DCN, MS, RD; Laura Byham-Gray, PhD, RD; Robert Denmark, PhD; Peter J. Winkle, MD

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ABSTRACT

Background Prior studies have provided evidence that lifestyle change prevents or delays the occurrence of type 2 diabetes mellitus. The challenge is to translate research evidence for type 2 diabetes mellitus prevention into health care settings.

Objective We investigated the effect of medical nutrition therapy (MNT) compared with usual care on fasting plasma glucose values, glycated hemoglobin (HbA1c), serum lipid levels, and Diabetes Risk Score, from baseline to the end of a 12-week intervention in overweight or obese adults with prediabetes.

Design Prospective, randomized, parallel group study of 76 adults with impaired fasting plasma glucose or an HbA1c of 5.7% to 6.4%, recruited between April 2010 and May 2011 who completed a 12-week intervention period.

Main outcome measures The primary outcome measure was fasting plasma glucose. Secondary outcome measures were HbA1c, serum lipid levels, and Diabetes Risk Score.

Statistical analyses A factorial repeated measures analysis of variance was used to make comparisons between the two groups (the MNT and usual care groups) and two measures of time (baseline and 12 weeks postintervention). Data analysis was performed using the Statistical Package for the Social Sciences (release 19.0, 2010, SPSS Inc).

Results There was a significant interaction for group assignment and HbA1c (P=0.01), with the MNT group experiencing significantly lower HbA1c levels than the usual care group (5.79% vs 6.01%) after the 12-week intervention. There was a significant interaction for group assignment and Diabetes Risk Score (P=0.001). Diabetes Risk Score for the MNT group decreased from 17.54±3.69 to 15.31±3.79 compared with the usual care group score, which went from 17.23±4.69 to 16.83±4.73. Regardless of group assignment, both groups experienced a reduction in total cholesterol (P=0.01) and low-density lipoprotein cholesterol (P=0.04) level.

Conclusions The results demonstrate that individualized MNT is effective in decreasing HbA1c level in patients diagnosed with prediabetes.
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AS OF 2011, THE PREVALENCE OF DIAGNOSED AND undiagnosed diabetes was estimated to be 25.8 million in the United States.[1] It is the seventh leading cause of death in the United States and is a major cause of cardiovascular disease.[1] The direct and indirect costs of the disease are estimated to be $174 billion annually.[2] The number of Americans with diagnosed diabetes has more than tripled from 1980 through 2011 from 5.6 million to 20.9 million.[1] The prevalence of diabetes has been steadily increasing, which is reflective of an aging population, rising incidence of overweight and obesity, improved methods of detection, and growing minority populations with higher rates of diabetes.[3] Type 2 diabetes mellitus is more prevalent among American Indians (14.2%), non-Hispanic blacks (12.6%), Hispanic Americans (11.8%), and Asian Americans (8.4%) compared with non-Hispanic whites (7.1%).[1]

With the increasing prevalence of diabetes and its associated economic burden, the pathogenesis of prediabetes has sparked considerable research interest. During 2005-2008, 35% of US adults aged 20 years or older had prediabetes, which is an estimated 79 million Americans.[1] Individuals with prediabetes may have impaired fasting glucose (IFG), which is defined as fasting plasma glucose (FPG) levels of 100 to 125 mg/dL (5.55 to 6.94 mmol/L), or impaired glucose tolerance (2-hour oral glucose tolerance test values of 140 to 199 mg/dL [7.77 to 11.04 mmol/L]), or glycated hemoglobin (HbA1c) level of 5.7% to 6.4%.[4,5] Patients with prediabetes have an increased risk of developing type 2 diabetes and cardiovascular disease.[5] In a

systematic review by Zhang and colleagues,[6] the level of HbA1c appears to have a continuous association with diabetes risk. Persons with an HbA1c ≥6.0% have a very high risk of developing diabetes with 5-year risks ranging from 25% to 50%.[6]

Landmark studies such as the Diabetes Prevention Study, the Finnish Diabetes Prevention Study, and the Da Qing Impaired Glucose Tolerance and Diabetes Study provide evidence that lifestyle change prevents or delays the occurrence of type 2 diabetes.[7-9] The US Diabetes Prevention Program reported that the incidence of type 2 diabetes was reduced by 58% in the lifestyle group compared with 31% in the metformin group after 2.8 years.[7] The Finnish Diabetes Prevention Study[8] also found a 58% reduction in the incidence of type 2 diabetes after 3.2 years, and the Da Qing Impaired Glucose Tolerance study[9] found that diet and/or exercise interventions led to a significant decrease in the incidence of diabetes over 6 years. The Da Qing study[9] resulted in the incidence of diabetes being reduced by 33% in the diet-only group, 47% in the exercise-only group, and 38% in the diet-plus exercise group.

The 2012 Standards of Medical Care in Diabetes recommends that individuals who have pre-diabetes should receive individualized medical nutrition therapy (MNT) as needed to achieve treatment goals, preferably by a registered dietitian nutritionist (RDN).[5] Level A recommendations from randomly controlled clinical trials find that structured programs that emphasize lifestyle changes that include moderate weight loss (7% body weight) and regular physical activity (150 minutes/week), with strategies to reduce calories and dietary fat may reduce the risk for developing type 2 diabetes.[5] Level B recommendations from well-conducted cohort studies report individuals should be encouraged to achieve the US Department of Agriculture recommendation for dietary fiber (14 g fiber/1,000 kcal) and include foods containing whole grains (one-half of grain intake) to improve metabolic control.[5]

MNT is an integral component of diabetes management. However, the Centers for Medicare and Medicaid Services currently does not cover treatment of prediabetes. The effectiveness of MNT in patients with prediabetes has not been studied using the 3 hours of therapy approved by the Centers for Medicare and Medicaid Services for persons with type 2 diabetes. The purpose of our pilot study was to investigate the effect of MNT in overweight or obese adults with prediabetes compared with usual care on fasting plasma glucose values, HbA1c, serum lipid levels, and Diabetes Risk Score, from baseline to the end of a 12-week intervention.

METHODS

Study Sample

This prospective randomized, parallel group study involved overweight or obese adult men and women, aged 18 years or older, with IFG or a HbA1c 5.7% to 6.4%, at Anaheim Clinical Trials, located in Anaheim, CA. Adults eligible for study participation were recruited between April 2010 and May 2011 for the prospective treatment and usual care groups. Participants were recruited from Anaheim, CA, and nearby communities. Anaheim is an ethnically diverse city and its demographics include 52.8% Hispanics or Latinos with 27.5% non-Hispanic white.[10] Because of its ethnic diversity, Anaheim has a higher percentage of residents at risk for prediabetes.

Eighty-one patients were included for the treatment and usual care groups. Inclusion criteria included male or female patients aged 18 years and older; no previous history or treatment for type 2 diabetes; IFG as defined as fasting plasma glucose >100 mg/dL (5.55 mmol/L) and <126 mg/dL (6.99 mmol/L) or HbA1c 5.7% to 6.4%; body mass index (BMI) 25 or higher; and are not already regularly active (defined as >30 minutes a day, 5 days a week of moderate intensity physical activity). Exclusion criteria included a history of type 2 diabetes and/or use of antidiabetes medications; concomitant medication known to interfere with glucose metabolism, such as systemic corticosteroids; use of weight loss drugs; pregnancy or breastfeeding; refusal or inability to give informed consent to participate in the study; hospitalized for heart disease, stroke, or transient ischemic attack during the past 6 months; and mental incapacity, unwillingness, or language barrier precluding adequate understanding or cooperation.

Study Methods

Participants were referred by physicians at Anaheim Clinical Trials, Internet advertising, and flyers distributed in the clinic waiting room. The protocol and consents were approved by the University of Medicine and Dentistry of New Jersey institutional review board and by the Aspire institutional review board. English and Spanish consent forms were both available to study participants.

At Visit 1, participants signed the California Bill of Rights and the informed consent before any study specific assessments. Participants were assigned a screening number and the number determined whether they would be assigned to MNT or usual care. Participants were not informed of their stratification until Visit 2 randomization. At the screening visit (Table 1), the following procedures were performed: review of inclusion/exclusion criteria, medical history, demographic data (ie, sex, age, race, ethnicity, family history of diabetes, and exercise habits), weight, height, BMI, waist circumference (WC), FPG, HbA1c, total cholesterol, high density lipoprotein (HDL) cholesterol, low-density lipoprotein (LDL) cholesterol, and triglycerides (TG). A urine pregnancy test was performed in women with childbearing potential. Vital signs (blood pressure and heart rate) were measured and a physical exam by a physician or physician assistant was performed. Hypertension was defined as taking an antihypertensive medication or having a blood pressure >130/80 mm Hg on two occasions at Visit 1 and at Visit 2. Dyslipidemia was defined as taking an antidyslipidemia medication, or an elevation of total cholesterol, LDL cholesterol, or TG concentrations, or a decrease in HDL cholesterol level. Clinical judgment by a physician or physician assistant was used to evaluate participants before recommending an exercise program. Participants completed the Diabetes Risk Score and the Diabetes Risk Calculator (DRC) questionnaires.

At Visit 2, participants who met the inclusion/exclusion criteria were randomized in the study to MNT or usual care. Participants in the usual care group would return after 12 weeks to complete a final visit. Participants randomized to MNT would receive 60 minutes of individualized MNT at Visit 2 by an RDN. A baseline 24-hour dietary recall was collected from the MNT group. Treatment participants were dispensed