

The Evidence for the Effectiveness of Medical Nutrition Therapy in Diabetes Management

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Numerous advances in diabetes management and medical nutrition therapy (MNT) for individuals with diabetes make this an exciting time. Historically, a challenge to proving the benefit of MNT has been the lack of clinical and behavioral research. In recent years, however, evidence-based outcomes research that documents the clinical effectiveness of MNT in diabetes has been reported.

The term “medical nutrition therapy” was introduced in 1994 by the American Dietetic Association to better articulate the nutrition therapy process. It is defined as the use of specific nutrition services to treat an illness, injury, or condition and involves two phases: 1) assessment of the nutritional status of the client and 2) treatment, which includes nutrition therapy, counseling, and the use of specialized nutrition supplements (1). MNT for diabetes incorporates a process that, when implemented correctly, includes: 1) an *assessment* of the patient’s nutrition and diabetes self-management knowledge and skills; 2) identification and negotiation of individually designed nutrition goals; 3) nutrition *intervention* involving a careful match of both a meal-planning approach and educational materials to the patient’s needs, with flexibility in mind to have the plan be implemented by the patient; and 4) *evaluation* of outcomes and

ongoing monitoring. These four steps are necessary to assist patients in acquiring and maintaining the knowledge, skills, attitudes, behaviors, and commitment to successfully meet the challenges of daily diabetes self-management (2).

The primary purpose of this article is to review the evidence for the effectiveness of MNT in diabetes, both as an independent variable and in combination with other components of diabetes self-management training (DSMT). In addition, the recent studies that have demonstrated the effectiveness of lifestyle intervention, which included MNT, in preventing type 2 diabetes will be highlighted. Evidence from several studies that supports the cost-effectiveness of MNT in diabetes will also be presented.

Evidence for the clinical effectiveness of MNT in diabetes

To determine the clinical- and cost-effectiveness of MNT as a potential preventative benefit in the Medicare program, the 105th U.S. Congress, in the Balanced Budget Act of 1997, requested that a study be conducted by the Institute of Medicine (IOM) of the National Academy of Sciences. To complete their study, the IOM held a number of meetings with public testimony and presented and conducted a comprehensive literature review.

In December 1999, IOM released their

report (3). In reference to diabetes, the report concluded that evidence exists demonstrating that MNT can improve clinical outcomes while possibly decreasing the cost of managing diabetes to Medicare. In conclusion, the IOM recommended to Congress that individualized MNT, provided by a registered dietitian with a physician referral, be a covered Medicare benefit as part of the multidisciplinary approach to diabetes care, which includes nutrition, exercise, blood glucose monitoring, and medications.

The IOM recommendation is consistent with the 2002 American Diabetes Association Position Statement “Evidence-Based Nutrition Principles and Recommendations for the Treatment and Prevention of Diabetes and Related Complications,” which states that, “because of the complexity of nutrition issues, it is recommended that a registered dietitian, knowledgeable and skilled in implementing nutrition therapy into diabetes management and education, be the team member providing medical nutrition therapy. However, it is essential that all team members be knowledgeable about nutrition therapy and is supportive of the person with diabetes who needs to make lifestyle changes” (4).

The evidence from randomized controlled trials, observational studies, and meta-analyses that nutrition intervention improves metabolic outcomes, such as blood glucose and HbA_{1c} levels in individuals with diabetes, is summarized in Table 1. Metabolic outcomes were improved in nutrition intervention studies, both as independent MNT and as part of overall DSMT. This evidence also suggests that MNT is most beneficial at initial diagnosis, but is effective at any time during the disease process, and that ongoing evaluation and intervention are essential.

Randomized controlled trials of MNT

The U.K. Prospective Diabetes Study (UKPDS) (5) was a randomized controlled trial that involved 30,444 newly diagnosed patients with type 2 diabetes at 15 centers. All treatment and control

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Abbreviations: DCCT, Diabetes Control and Complications Trial; DPP, Diabetes Prevention Program; DSMT, diabetes self-management training; IOM, Institute of Medicine; MNT, medical nutrition therapy; NPG, nutrition practice guideline; UKPDS, U.K. Prospective Diabetes Study.

A table elsewhere in this issue shows conventional and Système International (SI) units and conversion factors for many substances.

Table 1—Summary of evidence for nutrition therapy in diabetes

Type of intervention (Reference)	Study length	No. of subjects	Outcome
Randomized controlled trials			
MNT only			
UKPDS Group, 1990 (5)	3 months	3,042 newly diagnosed patients with type 2 diabetes	In 2,595 patients who received intensive nutrition therapy (447 were primary diet failures), HbA _{1c} decreased 1.9% (8.9 to 7%) during the 3 months before study randomization
Franz et al., 1995 (6)	6 months	179 persons with type 2 diabetes; 62 in comparison group; duration of diabetes: 4 years	HbA _{1c} at 6 months decreased 0.9% (8.3 to 7.4%) with nutrition practice guidelines care; HbA _{1c} decreased 0.7% (8.3 to 7.6%) with basic nutrition care; HbA _{1c} was unchanged in the comparison group with no nutrition intervention (8.2 to 8.4%)
Kulkarni et al., 1998 (7)	6 months	54 patients with type 1 diabetes; newly diagnosed	HbA _{1c} at 3 months decreased 1.0% (9.2 to 8.2%) with nutrition practice guideline care and 0.3% (9.5 to 9.2%) in usual nutrition care group
MNT in combination with DSMT			
Glasgow et al., 1992 (8)	6 months	162 type 2 diabetic patients over the age of 60 years	HbA _{1c} decreased from 7.4 to 6.4% in control-intervention crossover group while the intervention-control crossover group had a rebound effect; intervention group had a multidisciplinary team with an RD who provided MNT
Sadur et al., 1999 (9)	6 months	185 adult patients with diabetes	97 patients received multidisciplinary care and 88 patients received usual care by primary care. MD; HbA _{1c} decreased 1.3% in the multidisciplinary care group compared with 0.2% in the usual care group; intervention group had a multidisciplinary team with an RD who provided MNT
Observational studies			
Cross-sectional survey			
Delahanty and Halford, 1993 (10)	9 years	623 patients with type 1	Patients who reported following their meal plan >90% of the time had an average HbA _{1c} level 0.9% lower than subjects who followed their meal plan <45% of the time
Expert opinion			
DCCT Research Group, 1993 (11)			DCCT group recognized the importance of the role of the RD in educating patients on nutrition and adherence to achieve A1c goals; RD is key member of the team
Franz, 1994 (12)			DCCT made apparent that RDs and RNs were extremely important members of the team in co-managing and educating patients
Chart audit			
Johnson and Valera, 1995 (13)	6 months	19 patients with type 2 diabetes	At 6 months, blood glucose levels decreased 50% in 76 of patients receiving nutrition therapy by an RD. Mean total weight reduction was ~5 pounds
Johnson and Thomas, 2001 (14)	1 year	162 adult patients	MNT intervention decreased HbA _{1c} levels 20%, bringing mean levels <8% compared with subjects without MNT intervention who had a 2% decrease in HbA _{1c} levels
Retrospective chart review			
Christensen et al., 2000 (15)	3 months	102 patients (15 type 1 and 85 type 2 diabetic patients with duration of diabetes >6 months)	HbA _{1c} levels decreased 1.6% (9.3 to 7.7%) after referral to an RD
Meta-analyses of trials			
Brown, 1996, 1990 (16, 17)		89 studies	Educational intervention and weight loss outcomes; MNT had statistically significant positive impact on weight loss and metabolic control
Padgett et al., 1988 (18)		7,451 patients	Educational and psychosocial interventions in management of diabetes (including MNT, SMBG, exercise, and relaxation); nutrition education showed strongest effect
Norris et al., 2001 (19)		72 studies	Positive effects of self-management training on knowledge, frequency and accuracy of self-monitoring of blood glucose, self-reported dietary habits, and glycemic control were demonstrated in studies with short follow-up (<6 months)

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groups received nutrition counseling from a dietitian upon study entry until 3 months, at which time they were randomized into intensive or conventional therapy. During the initial period of the study when nutrition counseling was the primary intervention, the mean HbA_{1c} decreased by 1.9% (from ~9 to ~7%), fasting plasma glucose was reduced by 46 mg/dl, and there were average weight losses of ~5 kg after 3 months.

Franz et al. (6) completed a randomized, controlled trial in 179 individuals with type 2 diabetes, comparing the usual nutrition care consisting of only one visit with a more intensive nutrition intervention, which included at least three visits with a dietitian. The results concluded that with more intensive nutrition intervention, changes in lifestyle can lead to significant improvements in glucose control. The fasting plasma glucose level decreased by 50–100 mg/dl and the HbA_{1c} dropped by 1–2%. The average duration of diabetes for all subjects was 4 years and the decrease in HbA_{1c} was 0.9% (from 8.3 to 7.4%). In the subgroup of subjects with a duration of diabetes <1 year, the decrease in HbA_{1c} was 1.9% (from 8.8 to 6.9%). By 6 weeks to 3 months, it was known if nutrition intervention had achieved target blood glucose goals; if it had not, the dietitian made recommendations for changes in medications.

In a prospective randomized trial, Kulkarni et al. (7) examined the effect of using nutrition practice guidelines in patients with type 1 diabetes, as compared with the use of standard nutrition intervention in a control group. The patients who received intervention incorporating the nutrition practice guidelines achieved a greater reduction in HbA_{1c} (1.0 vs. 0.33%) than those patients who received standard nutrition intervention. Dietitians who incorporated the nutrition practice guidelines with patients were more likely to conduct a nutrition assessment and paid more attention to glycemic control goals, which contributed to the positive outcomes.

Randomized controlled trials of MNT combined with DSMT

Using a cross-over design, Glasgow et al. (8) studied 162 type 2 diabetic patients over the age of 60 years using a multidisciplinary team that included a dietitian. There was a significant reduction in caloric intake and percentage of calories from fat in the inter-

vention group compared with the control group. When control patients crossed over to the intervention group, their HbA_{1c} levels decreased from 7.4 to 6.4% while the intervention group had a rebound effect, with their HbA_{1c} results returning to prestudy levels.

Sadur et al. (9) published the results of a randomized controlled trial with 185 patients participating in a health maintenance organization. A total of 97 patients received care from a multidisciplinary team (dietitian, nurse, psychologist, pharmacist) in cluster-visit settings (10–18 patients per month for 6 months) compared with 88 patients who received usual care provided by primary care physicians. HbA_{1c} decreased by 1.3% in the intervention group compared with 0.2% in the control subjects. Self-care practices and self-efficacy improved significantly and hospital admissions and outpatient use were significantly lower for the intervention group.

Observational studies

In the Diabetes Control and Complications Trial (DCCT) study, Delahanty and Halford (10) reported the results of a cross-sectional survey intended to examine the role of nutrition behaviors in achieving improved glycemic control in 623 intensively treated patients with type 1 diabetes. The control and intervention groups both received counseling by a dietitian; however, the control group received nutrition counseling every 6 months and the intensive management group received nutrition counseling every month. The four nutrition behaviors associated with clinically significant reductions in HbA_{1c} (0.9%) were:

- adherence to prescribed meal and snack plan
- adjustment of insulin dose in response to meal size
- prompt treatment of hyperglycemia
- avoidance of overtreatment of hypoglycemia

In addition, the DCCT Trial Research Group (11) published an expert opinion statement recognizing the importance of the dietitian as a team member in educating patients on nutrition and adherence to achieve HbA_{1c} goals. Franz et al. (12) also published an expert opinion highlighting the changing roles of the RN, RD, and MD and emphasizing the importance of dieti-

tians and nurses as members of the diabetes care team in comanaging and educating patients.

Johnson and Valera (13) completed a 6-month retrospective chart audit of outcomes in 21 patients with type 2 diabetes who had completed three individual visits with an RD. At 6 months, blood glucose levels decreased 33.5% in patients receiving nutrition therapy by an RD. The mean total weight reduction was ~2.05 kg. Of the 85% of patients who were on oral medication or insulin at the initiation of the study, approximately half (44%) had less or no need for medication at the 6-month end point of the chart audit.

In 2001, Johnson and Thomas (14) reported the results of a 12-month retrospective chart audit with 162 adults patients with diabetes, 81 of whom received MNT intervention with at least two visits from an RD. The remaining subjects served as a nonintervention group and were chosen by random selection from a registry of diabetic patients who had never seen an RD. In the patients who received MNT intervention, HbA_{1c} levels decreased 20% (–2.14 units), bringing mean levels to <8%. In comparison, subjects without MNT intervention had a 2% decrease in HbA_{1c} levels (–0.2 units), with mean levels remaining >8%.

A retrospective chart review was conducted by Christensen et al. (15) on 102 patients (15 with type 1 diabetes and 87 with type 2 diabetes) to determine the contribution of diabetes MNT and DSMT conducted by dietitians in lowering HbA_{1c} values. Patients had a minimum of two visits with a dietitian, which were typically scheduled 2 weeks apart. There was a significant difference (1.6%) between mean pre-education HbA_{1c} level (9.32%) and mean post-education HbA_{1c} level (7.74%) measured at 3 months.

Meta-analyses of trials

Brown and colleagues (16,17) completed a meta-analysis of 89 studies of educational interventions and outcomes specific to weight loss in diabetes care. An important highlight of the results from these findings is that nutrition therapy alone had the largest statistically significant impact on weight loss and metabolic control. The combination strategy of nutrition and behavioral therapy plus exercise had a small effect on body weight, but a very significant impact on HbA_{1c}. These findings lend support to the effectiveness

of diabetes patient education in improving patient outcomes.

In a review of the effects of educational and psychosocial interventions in the management of diabetes (including education and skill training in diabetes, nutrition, self-monitoring, exercise, and relaxation) in 7,451 patients, Padgett et al. (18) found that nutrition education showed the strongest effect and relaxation training showed the weakest effect.

In March 2001, Norris et al. (19) published a systematic review of the effectiveness of DSMT in type 2 diabetes. The results of 72 randomized controlled trials were identified. There were positive effects of DSMT on knowledge, frequency, and accuracy of self-monitoring of blood glucose, self-reported dietary habits, and glycemic control in studies with short-term follow-up of <6 months. With longer follow-up, interventions that used regular reinforcement throughout follow-up were sometimes effective in improving glycemic control. Educational interventions that involved patient collaboration were thought to be more effective than didactic interventions in improving glycemic control, weight, and lipid profiles. The authors concluded that there is evidence to support the short-term effectiveness of DSMT in type 2 diabetes, but further research is needed to assess the effectiveness of self-management intervention on sustained glycemic control and cardiovascular disease risk factors.

Summary of clinical effectiveness studies

While there are few randomized controlled trials in which nutrition is the only variable (6,7), there are many studies that demonstrate the effectiveness of multidisciplinary diabetes education on improved glycemic control that include nutrition as a component. While these studies demonstrated improved outcomes, it is difficult to discern benefits that can specifically be attributed to MNT alone. However, meta-analyses studies looking at diabetes education and a variety of weight loss methods have shown that nutrition intervention has the largest statistically significant effect on metabolic control and weight loss (16–18). In addition, these meta-analyses studies have shown that diabetes education in general is effective in improving knowledge, skills, psychosocial adjustment, and metabolic control (16–19). Overall, the evidence in many types of studies involving nutrition

therapy in the management of diabetes is supportive of nutrition intervention.

Evidence for prevention of diabetes

Two recent studies (20,21) have shown that type 2 diabetes can be prevented by lifestyle interventions in subjects who are at high risk for diabetes. In the Finland Diabetes Prevention Study, published in May 2001 (20), 522 overweight subjects with impaired glucose tolerance were randomly assigned to an intervention or control group. The intervention group received individualized counseling to reduce weight (seven sessions the first year and every 3 months for the remainder of study), to decrease intake of total and saturated fat, and to increase intake of fiber and physical activity. Subjects were followed for 3.2 years and received an oral glucose tolerance test (OGTT) annually. Results at the end of 1 year showed a weight loss of 4.2 and 0.8 kg for the intervention and control groups, respectively. The incidence of diabetes after 4 years was 11% in the intervention group and 23% in the control group. During the study, the risk of diabetes was reduced by 58% in the intervention group.

The initial results of a similar study, the Diabetes Prevention Program (DPP), a multicenter National Institutes of Health study, suggest that type 2 diabetes can be prevented and delayed (21). The DPP was a randomized trial involving more than 3,200 adults who were >25 years of age and who were at increased risk of developing type 2 diabetes (i.e., having impaired glucose tolerance, being overweight, and having a family history of type 2 diabetes). The study involved a control group (standard care plus a placebo pill) and two intervention groups: one that received a intensive lifestyle modification (healthy diet, moderate physical activity of 30 min/day for 5 days/week) and one that received standard care plus an oral diabetes agent (Metformin). The major study findings indicate that participants in the intensive lifestyle modification group reduced their risk of developing diabetes by 58% compared with the medication intervention group who reduced their risk by 31%. Even more dramatic was the finding that individuals over 60 years of age in the intensive lifestyle modification group decrease their incidence of developing type 2 diabetes by 71%.

Economic support for MNT

In a econometric study of 12,308 patients with diabetes, Sheils et al. (22) measured the potential savings from MNT and estimated the net cost to Medicare of covering these services for Medicare enrollees. Differences in health care utilization levels of individuals with diabetes, cardiovascular disease, and renal disease were estimated for hospital discharges, physician visits, and outpatient visits for those who did and did not receive MNT. MNT was associated with a reduction in utilization of hospital services of 9.5% for patients with diabetes. Also, utilization of physician services declined by 23.5% for individuals with diabetes who received MNT. The authors concluded that after an initial period of implementation, coverage for MNT can result in a net reduction in health services utilization and costs. In individuals aged 55 years and older, the savings will actually exceed the cost of providing the MNT benefit.

Franz et al. (23) evaluated the cost-effectiveness of implementing MNT in type 2 diabetes. The cost of unit of change in fasting plasma glucose (1 mg/dl) from entry to 6 months was determined. The intensive nutrition intervention had a cost-effectiveness ratio of \$4.20 compared with usual nutrition care with a cost-effectiveness ratio of \$5.32. These findings suggest that individualized nutrition interventions can be delivered by dietitians with a reasonable investment of resources and that the cost-effectiveness is enhanced when dietitians are engaged in active decision-making regarding intervention based on patient needs.

Outcome studies lead to development of nutrition practice guidelines

Nutrition practice guidelines (NPGs) define the “best” nutrition care for individuals with diabetes. NPGs are evidence-based and are descriptions of diabetes nutrition care that results in positive health outcomes. NPGs for type 1, type 2, and gestational diabetes have been developed, field tested, and published by the American Dietetic Association and are available online through their website at www.eatright.org. These NPGs compare “best” nutrition care for patients with diabetes with “usual” or basic nutrition care. As shown in the NPGs, the role of the dietitian involves more than tailoring a meal plan; rather, it involves integrating

nutrition with the medical and behavioral care of the individual. Thus, the role of the dietitian is expanded by communicating closely with other health care professionals, focusing on blood glucose patterns as well as overall diabetes management, and serving as a case manager with diabetes patients. When NPGs were implemented, HbA_{1c} was reduced by an average of 1–2% in these outcome studies (6,7).

Outcome studies lead to expanded coverage for MNT

While it is well accepted and promoted that MNT is a critical element in the successful self-management of diabetes, the lack of reimbursement/coverage has made it difficult for individuals with diabetes to obtain MNT on an outpatient basis. Though hurdles still exist, the situation has improved over the last few years due to the passage of both federal and state laws and the recognition by some insurance companies that the coverage of this service is clinically and cost-effective.

At the federal level, Medicare beneficiaries with diabetes, who are eligible according to the Medicare guidelines (www.cms.gov), can be covered for a minimal amount (10 h initially and 2 h annually) of outpatient DSMT, which includes MNT. To be eligible for reimbursement, the provider of DSMT must be an American Diabetes Association Recognized Education Program (www.diabetes.org). DMST services must be prescribed by the referring physician or another non-physician qualified health care provider.

In addition, a new Medicare benefit for MNT for diabetes (including gestational diabetes) and renal disease was signed into law in 2000 and went into effect in January 2002. The detailed regulations regarding eligibility, hours of service, etc., were published in the 2002 Physician Fee Schedule (PFS) in the 1 November 2001 *Federal Register*. Detailed information is available on the American Dietetic Association website at www.eatright.org.

Forty-six states now have laws that mandate that private insurance plans and managed care organizations cover DSMT, inclusive of MNT, for people with type 1, type 2, and gestational diabetes. These laws generally affect ~30% of the population. Detailed information about each of the laws is available in *The Diabetes State*

Law Manual, American Diabetes Association and/or on the American Diabetes Association website (www.diabetes.org) in the Advocacy section. These laws do not cover the Medicaid or Medicare populations. They also do not cover people who have their health care coverage through a self-funded employer health plan.

As the role of nutrition in disease management has increased, large employer health plans and other types of health plans are recognizing the importance of providing MNT. Therefore, the number of patients who do have some coverage for MNT for diabetes has expanded. Individuals with diabetes should be encouraged to contact their health plan to determine their benefits for this service. A referral and/or letter from a physician, documenting the need for and importance of MNT, can also assist in improving reimbursement for this service.

Summary

Evidence-based research strongly suggests that MNT provided by a registered dietitian who is experienced in the management of diabetes is clinically effective. Randomized controlled nutrition therapy outcome studies have documented decreases in HbA_{1c} of ~1% in newly diagnosed type 1 diabetes, 2% in newly diagnosed type 2 diabetes, and 1% in type 2 diabetes with an average duration of 4 years. MNT should be considered as monotherapy, along with physical activity, in the initial treatment of type 2 diabetes, provided the person has a fasting plasma glucose <200 mg/dl. Individuals with type 2 diabetes who cannot achieve optimal control with MNT and whose disease may be progressing due to β -cell failure should be prescribed blood glucose-lowering medication, along with additional encouragement to achieve goals of MNT and physical activity. As R. Holman (Oxford, U.K.) stated in a discussion of the UKPDS findings, “if the real problem is the progressive decrease in β -cell function, it is our duty to explain this and not castigate these individuals because they have failed to diet” (24). Despite the fact that the effective promotion of healthy eating and physical activity is challenging in our society, it is now well documented that MNT does make a difference.

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