

Effect of Medical Nutrition Therapy for Patients With Type 2 Diabetes in a Low-/No-Cost Clinic: A Propensity Score–Matched Cohort Study

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■ ABSTRACT

Background. Although many studies have been conducted regarding the effectiveness of medical nutrition therapy (MNT) for type 2 diabetes management, less is known about the effectiveness of MNT for low-income adults. This study evaluated the contribution of MNT in improving A1C and blood pressure in a population of low-income adults with type 2 diabetes.

Methods. This was a population-based, propensity score–matched cohort study using provincial health data from Altoona, Blair County, Pa. Patients who had been diagnosed with type 2 diabetes for at least 6 months before March 2014 were selected from two separate clinics that serve low-income populations. Patients who received MNT ($n = 81$) from a registered dietitian were compared to a matched group of patients who received primary care alone ($n = 143$). Outcome measures were A1C and systolic and diastolic blood pressure. The follow-up period was 1 year.

Results. Improvements in A1C and systolic and diastolic blood pressure were statistically significant for patients who received MNT at uniform 3-month intervals through 1 year. At the 1-year follow-up, A1C reduction was -0.8% ($P < 0.01$), systolic blood pressure reduction was -8.2 mmHg ($P < 0.01$), and diastolic blood pressure reduction was -4.3 mmHg ($P < 0.05$).

Conclusion. Although low-income individuals encounter a variety of barriers that reduce their capacity for success with and adherence to MNT, provision of nutrition therapy services by a registered dietitian experienced in addressing these barriers can be an effective addition to the existing medical components of type 2 diabetes care.

Medical and nutrition experts agree that medical nutrition therapy (MNT) promotes optimal health and prevention of disease progression in chronically ill patients (1). It is well documented that MNT can improve glycemic control by reducing A1C and, when used with other components of diabetes care, can further improve clinical and metabolic outcomes, resulting in reduced comorbidities and hospitalizations (2–6). However, many of the problems with health and health care in the United States are directly relat-

ed to a lack of available nutritious food options for low-income individuals, resulting in potentially costly health disparities that could be avoided by meeting basic nutritional needs (7).

MNT and diabetes self-management education are integral parts of the treatment and self-management of diabetes. Failure to implement such strategies will increase pharmacological requirements or result in suboptimal glycemic control. However, adoption of MNT requires concentrated behavior change and mastery of multifaceted information,

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which can pose a significant barrier to attaining successful glycemic control, particularly among low-income patients with diabetes (8,9). Numerous resource-related, attitudinal, and knowledge-based barriers have been identified that often vary based on sociodemographic characteristics (10,11).

The goals of MNT in diabetes management are generally twofold: to maintain or improve quality of life and nutritional and physiological health and to delay or prevent long-term complications of diabetes and associated comorbid conditions. There is limited clinical evidence about the effectiveness of MNT programs designed for low-income patients with diabetes in a primary care setting. MNT provided by a registered dietitian (RD) with expertise in diabetes self-management in an individual setting and with frequent follow-up (i.e., every 3 months) produced better clinical outcomes than MNT provided in group classes among lower-income adults. Conversely, group classes appeared to be more effective than individual therapy among higher-income adults when they incorporated principles of adult education, including hands-on activities, problem-solving, and group discussions (12,13). Among minority groups with type 2 diabetes, culturally appropriate peer education was shown to improve A1C, as well as general nutrition knowledge and diabetes self-management skills and adherence. Group-specific Internet-based self-management education was also shown to improve glycemic control (14–16). MNT programs designed for low-income populations should evaluate the presence and types of barriers to healthy eating (e.g., cost and lack of knowledge) and work toward individualized solutions to facilitate behavior change (9).

The aim of this study was to determine the empirically observed change in A1C in patients with type 2 diabetes after they received MNT delivered by an RD in a low- or no-cost clinic

setting. Further objectives were to assess the effectiveness of MNT in reducing systolic and diastolic blood pressure.

Research Design and Methods

A retrospective chart review was performed on patients' medical records at two separate clinics that serve primarily low-income individuals. Both clinics treat type 2 diabetes according to the American Association of Clinical Endocrinologists/American College of Endocrinology Comprehensive Diabetes Management Algorithm (17). One clinic instituted a diabetes nutrition counseling/education program designed to treat low-income individuals and to address barriers to dietary adherence specific to the program's patient population.

The study sample included 224 patients from two distinct low- or no-cost clinics in Altoona, Blair County, Pa.: the Altoona Center for Health (ACH; $n = 143$) and the Empower³ clinic ($n = 81$). ACH is a federally qualified health center (FQHC) that accepts patients who qualify for Medicaid; each patient's annual household income must be $\leq 133\%$ of the federal poverty level (FPL). In 2014, the FPL was income of \$23,850 per year for a family of four. As an FQHC, ACH provides primary care to uninsured and underinsured patients regardless of their ability to pay. If applicable, ACH collects patient fees at the point of service using a sliding fee scale based on household income.

Although Empower³ is not an FQHC, nearly 60% of its patients have household incomes $\leq 133\%$ of the FPL. The Empower³ clinic provides access to low- or no-cost health care for ~5,000 patients annually. It is a hospital-based primary care clinic that accepts patients regardless of health status who have no primary care insurance and have a household income $\leq 300\%$ of the FPL. The fee structure for Empower³ differs from that of ACH. For unlimited visits to Empower³ with \$0 copayments and

deductibles, patients pay a monthly capitation fee based on household income. Patients with income up to 150% of the FPL pay no fee; those with income up to 300% of FPL pay \$99 per month. Small business owners can also purchase an employee-based plan for \$169 per month per employee, provided each employee's income does not exceed 300% of FPL.

Intervention and Comparison Groups

Patients from either clinic were eligible for inclusion in the sample if they were diagnosed with type 2 diabetes and had started medication at least 6 months before the March 2014 starting date of MNT at the Empower³ clinic. Patients who had incomplete data, were pregnant, or had end-stage renal disease were excluded. All sample patients were diagnosed using A1C ($\geq 7.0\%$ at diagnosis). No sample patients exhibited criteria for type 1 diabetes. Baseline measurements of A1C and blood pressure, defined as the latest test results before March 2014, were obtained for all sample patients via anonymized electronic medical records. In addition, we obtained supplementary data on patients' income percentage of FPL recorded at the date of the first office visit, sex, age, and ethnicity.

In April 2014, all Empower³ patients were referred to a newly established, in-house MNT program for management of their type 2 diabetes. Between April 2014 and July 2015, all intervention group patients completed a minimum of four one-on-one visits with Empower³'s RD. Medical records verified that each patient contact occurred. All clinic contacts occurred at ~3-month intervals. All sample patients were receiving ongoing medical treatment from their primary care physician in addition to the MNT provided to Empower³ patients. Thus, improvements in Empower³ patients' follow-up health outcomes cannot be attributed solely to MNT.

Limiting our sample to patients diagnosed with type 2 diabetes for ≥ 6 months before the start of MNT helped to control for the initial observed decline in A1C after the start of medication treatment.

Laboratory blood tests were performed for Empower³ patients before each scheduled meeting with the RD. Goal-setting to improve diabetes control was individualized and incorporated into each counseling session. These goals were individualized (e.g., exercise frequency, learning to read nutrition labels, or keeping a regular food diary) and designed

by the patients in consultation with the RD to manage blood glucose. Written educational materials were also provided to assist patients and their families with practical diet management, meal preparation, and exercise techniques.

The Empower³ program had two main goals. The first was to provide patients with a thorough understanding of established meal plans and meal preparation, as well as to address daily challenges specific to individuals operating on a tight budget. The second was to provide patients with a readily accessible sup-

port system. All patients enrolled in MNT were encouraged to visit the clinic for advice and support with no restrictions such as copayments or deductibles and no delays in securing appointments with clinic staff.

Results of Statistical Analysis

Because data collection was part of each clinic's treatment protocol, it was not possible to schedule follow-up measurements specific for this study. Therefore, test results were used for each patient at least 1 year after the April 2014 date on which the patient started MNT. For the ACH comparison group, we used the test results

TABLE 1. Patient Characteristics at Baseline and at the End of the 1-Year Study

	Full Sample ^a (n = 225)	Empower ³ Group ^a (n = 81)	ACH Group ^a (n = 143)
Age (years)	53.64 (8.74)	56.9 (7.8)**	51.8 (8.8)**
Male (n [%])	109 (48.4)	27 (33.3)	82 (57.3)
Nonwhite (n [%])	10 (4.4)	2 (2.2)	8 (5.6)
Body weight (lb)			
2014 baseline	230.6 (55.2)	235.1 (51.0)	229.7 (57.5)
2015 follow-up	229.4 (56.1)	233 (51.5)	228.9 (58.7)
2014-to-2015 change	-1.2 (15.0)	-2.1 (14.1)	-0.8 (18.4)
Total cholesterol (mg/dL)			
2014 baseline	185.5 (50.4)	183.5 (50.7)	186.6 (50.4)
2015 follow-up	184.54 (51.1)	181.4 (53.9)	187.2 (49.4)
2014-to-2015 change	-1.0 (45.3)	-2.1 (44.1)	0.6 (50.5)
Insulin treatment (n [%]) ^b	14 (6.25)	5 (6.2)	9 (6.3)
A1C (NGSP %)			
2014 baseline	8.2 (2.2)	8.2 (2.2)	8.3 (2.1)
2015 follow-up	8.3 (2.0)	7.8 (2.0)***	8.6 (1.9)***
2014-to-2015 change	0.1 (1.8)	-0.4 (1.2)***	0.3 (2.0)***
Systolic blood pressure (mmHg)			
2014 baseline	131.2 (16.0)	131.2 (16.0)	132.1 (16.0)
2015 follow-up	130.7 (15.8)	128.7 (14.0)**	132.8 (16.2)**
2014-to-2015 change	-0.5 (14.3)	-2.5 (11.6)*	0.7 (16.4)*
Diastolic blood pressure (mmHg)			
2014 baseline	79.4 (9.3)	79.1 (8.4)	80.2 (9.8)
2015 follow-up	79.3 (10.2)	77.8 (8.7)**	80.8 (10.9)**
2014-to-2015 change	-0.1 (8.9)	-1.3 (7.2)*	0.6 (9.9)*

^aReported as mean (SD) unless otherwise noted.

^bVariable did not change over the 1-year study period.

*Significant at <10%.

**Significant at <5%.

***Significant at <1%.

TABLE 2. Covariates of Study Participants at Baseline Used for Matching

	Unmatched/ Matched	Mean		Standardized Bias	P
		Empower ³	ACH		
Patient's income percentage of FPL	U	153.1	131	0.82	0.001
	M	139.5	134.2	0.03	0.342
Patient's age (years)	U	56.9	51.8	0.6	0.003
	M	56.7	57.0	0.03	0.874
Patient's percentage of FPL × age	U	8,726	5,962	0.97	0.001
	M	6,703	6,446	0.09	0.463
Patient is male: 1 = yes, 0 = no	U	0.33	0.57	0.5	0.001
	M	0.39	0.32	0.09	0.438
Patient is nonwhite: 1 = yes, 0 = no	U	0.02	0.06	0.24	0.111
	M	0.02	0.04	0.09	0.574

nearest to, but at least 1 year after, April 2014.

All study patients had at least one measurement of the specific outcome of interest in the 12-month period before and after the starting date of MNT. This process allowed us to capture baseline measures of A1C and blood pressure for all study patients and to follow the patients in each group forward in time to obtain 1-year follow-up measures. Clinical characteristics of patients at baseline and at the 1-year follow-up (2015) are shown in Table 1. No significant differences were found between the Empower³ and ACH groups in body weight, total cholesterol, insulin use, A1C, or systolic or diastolic blood pressure at baseline. However, the ACH group had higher proportions of males and younger patients than the Empower³ group. At the end of the 1-year study, Empower³ patients had significantly lower A1C (7.8 vs. 8.6%, $P < 0.01$), systolic blood pressure (128.7 vs. 132.8 mmHg, $P < 0.05$), and diastolic blood pressure (78.7 vs. 80.8 mmHg, $P < 0.05$) than the ACH patients.

Because a priori differences in patient characteristics between intervention and comparison groups can lead to biased inferences based on simple mean differences tests, we used propensity score matching to reduce potential bias and to estimate the average treatment effect for the

treated (ATT) (Empower³) group (18). A two-stage process similar to that developed by Rosenbaum and Rubin (19) was used to estimate the propensity score (the probability of receiving MNT) for each patient in the intervention and comparison groups. Using a binary logit model (20), we estimated the propensity of participating in MNT (i.e., enrollment in Empower³) based on a set of four observed covariates: the patient's baseline income percentage of FPL, age, sex, and ethnicity. We also included the interaction of income percentage of FPL and patient age (Table 2). Several specifications of the propensity score model were estimated using combinations and interactions of patient age, sex, ethnicity, insulin treatment, and income percentage of FPL. All covariates and interactions failing to achieve balance in matching were eliminated. Covariate balance achieved in matching was assessed by absolute standardized differences in covariates between patient groups. This criterion is more appropriate than simple means tests for assessing balance and is also an important measure of the quality of a propensity score model (21). The model shown in Table 2 was the best specification for our data; all covariates had absolute standardized differences < 0.1 .

All patients in the intervention group were matched to patients in the

comparison group based on their propensity score using a radius matching algorithm (22–24). Radius matching allows for greater precision than fixed nearest-neighbor matching in regions where many similar comparison observations are available, which can lead to smaller bias in the calculation of the ATT in regions where similar controls are sparse. Following Rosenbaum and Rubin (18), we used a caliper width equal to 0.25 of the standard deviation of the logit of the propensity score. Although Austin (25) recommended a caliper width not to exceed 0.2 of the logit standard deviation, we tested a range of caliper widths and found Rosenbaum and Rubin's recommendation superior for minimizing the remaining mean standardized bias and variance after matching on the propensity score for radius matching.

The matching covariates at study entry of both groups are displayed in Table 2. Systematic differences between the intervention and comparison groups at baseline, shown in Table 1, endorse the need for matching. Compared to the ACH group, which did not receive MNT, the Empower³ group had higher incomes (percentage of FPL 153.1 vs. 131%, $P < 0.01$) as well as proportionately fewer males ($P < 0.01$) and younger patients ($P < 0.05$). After matching, there were no significant differences between groups. Standardized differ-

TABLE 3. Estimated Effect of MNT on Treated Patients' A1C and Blood Pressure

Full Sample (n = 225)	Radius Matching (ATT)	Critical level of Γ	Kernel Matching (ATT)	Critical level of Γ
A1C (NGSP %)				
2015 follow-up	-0.8***	1.7	-0.7**	1.4
2014-to-2015 change	-0.7***	1.95	-0.8**	1.9
Systolic blood pressure (mmHg)				
2015 follow-up	-8.2***	1.8	-8.2**	1.5
2014-to-2015 change	-5.2**	1.5	-8.1**	1.5
Diastolic blood pressure (mmHg)				
2015 follow-up	-4.3**	1.9	-4.4**	1.8
2014-to-2015 change	-3.5***	1.8	-3.3*	1.8

Bootstrapped standard errors (1,000 replications) are used for significance testing. Γ = odds of differential assignment to treatment due to unobserved factors.

*Significant at <10%.

**Significant at <5%.

***Significant at <1%.

ences (bias) for each of the baseline variables used for matching were ≤ 0.1 , indicating that the two groups were reasonably well matched.

Propensity score-matched estimates of the 1-year effect of MNT on treated patients' outcome variables are presented in Table 3. For each outcome, Table 3 reports differences between Empower³ and ACH patients in both their 1-year (i.e., 2015) A1C and blood pressure levels and their changes in these levels between 2014 and 2015. For example, the row for A1C shows whether matched patients receiving or not receiving MNT displayed systematic differences in A1C in 2015 and differences in their relative change in A1C between 2014 and 2015. We evaluated changes in outcomes (i.e., difference in differences) to help eliminate possible bias resulting from unobserved heterogeneity that is time-invariant. The difference-in-differences matching estimator can be used correctly in this manner when estimating a treatment effect after initial implementation of a program or intervention (26–28). Statistical inferences about all ATT estimates reported in Table 3 used bootstrapped standard errors using 1,000 replications.

As shown in Table 3, there were significant differences between the two groups with respect to A1C at 1-year follow-up. When matched on their propensity to receive MNT, Empower³ patients revealed lower 2015 follow-up A1C (-0.8%, $P < 0.01$) and 2014-to-2015 A1C change (-0.7%, $P < 0.01$) than ACH patients not receiving MNT. In addition, Empower³ patients exhibited lower 2015 systolic (-8.2 mmHg, $P < 0.01$) and diastolic (-4.3 mmHg, $P < 0.05$) blood pressure than non-MNT patients. By comparison, ATT estimates for 2014-to-2015 systolic and diastolic blood pressure change were -5.2 mmHg ($P < 0.05$) and -3.5 mmHg ($P < 0.01$), respectively.

We evaluated sensitivity of our results in two ways. First, we re-estimated ATTs for all outcome variables using kernel matching to assess the robustness of our radius-matched results compared to an alternative matching algorithm (29). We then applied Rosenbaum's bounds method of sensitivity analysis (30) to both sets of matched estimates. Results based on kernel matching are presented in Table 3. For kernel matching, propensity scores were estimated using all covariates listed in Table 2 not including the indicator for nonwhite

patients, which failed to balance. All remaining covariates exhibited good balance (standardized differences < 0.09). ATT estimates using kernel matching compared well to the radius-matched results, although the kernel-matched results had slightly higher standard errors.

Regarding sensitivity to hidden bias, Rosenbaum (30) suggested a bounding approach to identify the critical level of influence (Γ) that a variable excluded from the model may reach before inferences from the matching exercise needed to be questioned. Critical levels of Γ are presented in Table 3 and ranged between 1.4 and 1.95 depending on the matching algorithm and outcome variable. This range implies that our analyses are insensitive to a bias that would influence the odds of enrolling in Empower³ (versus ACH) by a factor equal to the Γ levels. That is, for $\Gamma = 1.95$, we need to question our conclusion if an unobserved confounder almost doubled the odds ratio of Empower³ enrollment. We therefore considered our results to be reasonably robust against hidden bias.

Discussion

This study empirically evaluated the effect of a newly established nutrition

counseling and education program by a low-/no-cost clinic on A1C, total cholesterol, and blood pressure in patients with type 2 diabetes. Improvements in A1C and systolic and diastolic blood pressure were significant for patients who received MNT at uniform 3-month intervals for 1 year. The findings of this study support previous studies on improving A1C with diabetes nutrition and self-management education (1–6, 31–37). In addition, they support the contention that MNT can be an effective addition to existing medical components of care for type 2 diabetes (with or without concurrent hypertension) for low-income patients if patient-specific barriers to program adherence are adequately addressed.

Although it is well accepted that MNT is a critical element in the successful self-management of diabetes, lack of resources and/or insurance coverage has made it difficult for low-income individuals with diabetes to obtain outpatient MNT and, if obtained, to adhere to dietary guidelines. Diabetes education and management programs serving low-income populations should address barriers to healthy eating that are unique to that population (10). The RD at Empower³ used an individualized approach to the treatment of low-income patients with diabetes.

The RD served as team leader of the clinic's multidisciplinary diabetes treatment group, which included a primary care physician, physician's assistant, registered nurse, and on-site pharmacist. Each team member was involved to some extent in MNT program patients' overall diabetes management protocol. The team met regularly to discuss patients' successes and expressed concerns and how to adapt team-patient interactions or communications to strengthen patients' dietary adherence as part of their general treatment goals.

Consistent with the literature on dietary barriers (38,39), the cost of healthy food was the most frequently acknowledged barrier to dietary

adherence among Empower³ MNT participants. In response, the RD placed increased emphasis on how to shop for healthy foods with a limited budget during sessions with clinic patients. In addition, the RD communicated regularly with all MNT participants via phone, email, text messaging, or other means to provide them with up-to-date information about reduced-cost food options available at local markets, discount outlet stores, and local farmers' markets.

Beginning in 2014, the Patient Protection and Affordable Care Act (ACA) expanded coverage to millions of previously uninsured people through the expansion of Medicaid and the establishment of health insurance marketplaces. Recent data have indicated substantial gains in public and private insurance coverage and historic decreases in uninsured rates in the first and second years of the ACA. Coverage gains were especially large among low-income individuals living in states with expanded Medicaid services. Nevertheless, millions of people—roughly 28.5 million in 2015—remained without coverage (40).

Individuals in low-income working households represent a significant portion of the U.S. uninsured population and face limited health care options even if they qualify for Medicaid. Accordingly, uninsured individuals often delay or forego necessary primary and preventive health care services because of cost or other access constraints. Most policymakers, health care industry leaders, and providers agree that accessible primary care for the uninsured can be cost-saving in the long term because early and preventive care costs less than potentially higher future use of emergency department or inpatient services resulting from undertreated chronic health conditions. Thus, communities, hospitals, and health care providers will need to continue exploring new mechanisms

for providing primary care services to low-income populations.

Hospital-sponsored care programs for the uninsured such as the Empower³ clinic are becoming an increasingly visible component of the U.S. health care safety net, especially in light of continued high numbers of uninsured adults, increasing costs of health coverage in individual and employer-funded plans, and pressures on state budgets to continue to limit enrollment in Medicaid. The results of this study offer evidence that private- and/or public-sector investments in MNT designed to aggressively manage chronic health conditions such as type 2 diabetes in uninsured patients could result in significant cost savings, as well as better health and greater quality of life for low-income under- or uninsured individuals and families.

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Duality of Interest

Z.G. is medical director, founder, and part owner of Empower³ Center for Health, a for-profit clinic described in this article. No other potential conflicts of interest relevant to this article were reported.

Author Contributions

M.D.A. wrote the manuscript and researched the data. Z.G. obtained all data, contributed to discussion, and reviewed and edited the manuscript. P.M.I. researched data and reviewed and edited the manuscript. M.D.A. is the guarantor of this work and, as such, had full access to all of the anonymized data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

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