Original Article

Economic analysis of a diabetes-specific nutritional meal replacement for patients with type 2 diabetes

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This study extends nutritional intervention results reported by short-term clinical trials of a diabetes-specific nutritional meal replacement by assessing the ten-year impact of the interventions on patient outcomes and costs compared to usual care. We developed and validated a computer simulation of type 2 diabetes based on published data from major clinical trials. The model tracks patients through microvascular and macrovascular health states and reports cumulative costs and quality adjusted life years. We modeled different scenarios that include a diabetes-specific nutritional meal replacement as part of a structured lifestyle intervention, and also as the only difference between the intervention and usual care treatment groups, and compared them to usual care with diet and physical activity recommendations. We used sensitivity analysis to explore the robustness of results. When a diabetes-specific nutritional meal replacement is the only treatment difference and is considered an equal cost meal replacement, the diabetes-specific nutritional meal replacement interventions are less costly and more effective than usual care. As an added cost meal replacement, the diabetes-specific nutritional meal replacement has an incremental cost-effectiveness ratio between $50,414 and $55,036 depending on improvement in percent glycated hemoglobin. A hypothetical lifestyle intervention using a diabetes-specific nutritional meal replacement has an incremental cost-effectiveness ratio of $47,917. The diabetes-specific nutritional meal replacement was found to be cost-effective under the various conditions simulated.

Key Words: nutrition therapy, type 2 diabetes mellitus, computer simulation, cost analysis, quality adjusted life years

INTRODUCTION

Diabetes is a progressive disease, requiring regular medical care and intensive patient self-management to achieve and maintain blood glucose control, prevent acute complications and reduce the risk of long-term complications. Structured interventions including anti-hyperglycemic medications, diet, lifestyle and self-care are important to achieving and maintaining better blood glucose control. The percent glycated hemoglobin (A1c) is a key indicator of glycemic control as the value indicates the non-enzymatic attachment of glucose to hemoglobin over the previous three months. Major diabetes clinical trials have established a direct linkage between A1c and risks for retinopathy, nephropathy, and neuropathy.[1,2] The significance of the relationship between A1c and macrovascular end points has been questionable,[2-4] although the recent 10-year United Kingdom Prospective Diabetes Study (UKPDS) follow up indicates that the post-trial "legacy effect" of intensive glycemic control produces a significant reduction in the risk of myocardial infarction.[5]

Optimal glucose control as reflected by A1c levels is directly affected by both fasting and postprandial glucose, with postprandial glucose having the greatest effect at lower levels of A1c and fasting glucose at higher levels.[6] Additionally, evidence is mounting that postprandial glucose is an independent risk factor for cardiovascular disease.[7]

Careful attention to diet is an important way of improving postprandial glucose and long-term glycemia. Evidence that specific nutrition interventions improve blood glucose and A1c levels in individuals with diabetes has been previously reviewed.[8] The term "medical nutrition therapy" (MNT) describes specific nutrition interventions, usually consisting of nutrition counseling and nutrition therapy that may include specialized nutritional supplements.[9] Diabetes-specific nutritional products are designed to deliver quality nutrition and at the same time, minimize postprandial glucose response, typically in a portion-and-calorie-controlled manner. These nutritional products can be an integral component of medical nutrition therapy by improving postprandial glycemia and facilitating adherence to nutritional guidelines. A systematic review and meta-analysis of clinical trials has shown that short-term use of diabetes-specific nutritional supplements can significantly lower postprandial glucose levels and area under the glycemic curve.[10] Furthermore,

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when used to replace a meal in structured interventions, diabetes-specific nutritional meal replacements (DSNMR) can help individuals with type 2 diabetes reduce weight.[11,12]

One specialized nutritional supplement (Glucerna® SR, Abbott Laboratories, Chicago, IL) is formulated to be consistent with nutrition therapy guidelines containing low glycemic and slowly-digested carbohydrates, prebiotic fiber, and a lipid blend rich in monounsaturated fatty acids. Studies in patients with type 2 diabetes have shown that this nutritional supplement does not spike postprandial blood glucose levels compared to standard formula.[13] Longer trials have demonstrated that when used as a meal replacement as part of a diabetes management plan, this specialized DSNMR helps patients improve A1c, blood pressure, blood lipids, body weight and fat composition.[14-16] In one six-month trial, patients with type 2 diabetes using this DSNMR as part of an integrated diabetes management program achieved a 0.8% reduction in A1c compared to a reference group receiving only usual care intervention.[14] Noteworthy is that this A1c improvement is similar to that reported for patients receiving intensive glucose control in the UKPDS. Two other trials demonstrated smaller improvements in A1c of 0.3% and 0.5% after three months when patients using this specialized DSNMR were compared to control groups undergoing a similar intervention without a DSNMR.[15,16]

Despite the evidence supporting their role in diabetes management, DSNMR are frequently perceived as an economic burden. Because they are intended to replace less nutritionally-complete and higher-glycemic calories, when used as a meal replacement, DSNMR may become cost-neutral or cost-saving. Furthermore, by facilitating adherence to medical nutrition therapy guidelines, it is expected that additional savings would be gained in terms of better metabolic control and fewer long-term complications.

Because there are no long-term data, the objective of this paper is to extend the nutritional intervention results previously reported to assess the ten-year impact of the interventions in terms of patient outcomes and costs when compared to a standard of care including dietary and physical activity recommendations. We modeled different scenarios that include DSNMR as part of a structured lifestyle intervention, and alternatively as the only difference between the intervention and usual care treatment groups, and compared them to usual care with diet and physical activity recommendations.

MATERIALS AND METHODS

Model description

This economic analysis is supported by a computer simulation model designed to represent the costs and patient outcomes for a cohort of 1,000 type 2 diabetic patients. The model is a discrete individual-state transition model, constructed in the MedModel simulation environment (PROMODEL Corp., Orem, Utah, USA). We chose this particular modeling approach to allow measuring the effects of numerically small differences in A1c and also to explicitly represent individual variability. Because of the interdependence of the complications of type 2 diabetes, the model specifically allows patients to develop multiple complications and progress to more serious morbidities in each. For example, a patient could progress from non-proliferative retinopathy to proliferative retinopathy on the retinopathy pathway while also suffering from micro-albuminuria on the nephropathy pathway. Death from all causes can occur from any state, while death from myocardial infarction or stroke can only occur from those particular states.

At model start up, each patient is considered to possess unique attributes, and consistent with UKPDS data, patients are newly-diagnosed with an assumed duration of type 2 diabetes of less than one year, and are drug naïve. The model is set up to operate in annual time steps. At each time step, the model advances patient age and disease duration and dynamically computes the current A1c for each patient entity by increasing the value at a rate of 0.113% per year. This rate was derived using simple regression of mean A1c values reported at 5 year intervals for the UKPDS conventional care group. This rate was used for all care groups in our model scenarios because after an initial improvement of A1c due to intensive management, the rate of increase was shown to be consistent with the rate for the conventional care group.[2] As A1c increases over time, the new value is used to interpolate the probability of progressing to the next complication, or health state. The model separately evaluates whether a patient will advance to a more morbid state of each complication, remain in the current state, or return to a lower morbidity state if allowable. Probabilities that a patient would move from one state to another were derived from published UKPDS and Wisconsin Epidemiologic Study of Diabetic Retinopathy (WESDR) data.[1,2] The probabilities were inferred from the percent of patients who developed each particular complication over the period of time from initial enrollment to end of trial. For example, a prevalence of 5.1% at 9 years would have an annual probability of 0.6%.

Model validation

The model has been validated at mean A1c of 7.0% and 9.3%, based on published data from the UKPDS and WESDR trials. Model validation runs were set up to reflect the conditions that existed in the clinical trials. For example, model validation output was recorded at 9 years for nephropathy and neuropathy, 11 years for macrovascular complications, and elements of retinopathy were evaluated at 19 years. Reference values and model results are compared for the cohort from the beginning of the trial to the temporal point of assessment

Annual costs and utility values

Annual costs and utility values for each health state are shown in Table 1.[17-19] The costs are estimates of the direct medical costs of type 2 diabetes-related treatment, excluding indirect costs and medical costs related to other conditions. Utility values for each health state reflect the incremental reduction in health status resulting from complications. Utility values for each health state in each year are added to the base utility value of 0.689 to produce a unique measure of health status for each patient (e.g., where a value of 1.0 is equivalent to one year in perfect health, and a value of zero represents death). Cumulative cost and utility (expressed as quality adjusted

Table 1. Model inputs: costs and utilities

Disease State	First Year Cost ($)[†]	Subsequent Years Cost ($)[‡]	Utility (QALY)[§]	Reference
DM without complication	0	0	0.0	17,18
Non-proliferative retinopathy	0	0	0.0	17
Proliferative retinopathy	1,173	105	0.0	17
Macular edema	1,061	105	0.0	17
Blindness	5,139	5,139	-0.17	17,19
Microalbuminuria	88	21	0.0	17
Macroalbuminuria	93	31	-0.011	17,19
End-stage renal disease	51,617	51,617	-0.078	17,19
Peripheral neuropathy	519	519	-0.065	17,19
Amputation	42,321	1,521	-0.105	17,19
Coronary heart disease	8,399	2,169	-0.052	17,19
Myocardial infarction	42,334	2,340	-0.052	17,19
Stroke	56,061	18,709	-0.072	17,19
"Lifestyle" intervention	1,951	979	0.019	18,19
DSNMR as additional cost	365	365	0.0	

[†]First year costs are those associated with the acute episode and subsequent care in that year.
[‡]Subsequent year costs are cost of continued management for each year the patient remains in the particular state.
[§]Utility values for each health state occupied in a year are added to the base utility value of 0.689

life years, QALY) are computed by the model for each patient at each time step and then aggregated for the cohort. All costs are in U.S. dollars, have been inflated to year 2008, and costs and utilities are discounted at 3% per year, except where the discount rate has been set to zero in the sensitivity analysis.

Simulation scenarios

Two types of scenarios are simulated. In the first scenario type, we reproduce and extend the results of three clinical trials.[14-16] We compare a DSNMR structured intervention to usual care that includes dietary and physical activity advice. The scenario evaluates a 0.8% difference in mean A1c between the reference cohort (A1c 7.8%) and the DSNMR cohort (A1c 7.0%) as part of a structured intervention program as reported by Sun, et al.[14] We have assumed that clinical visit costs are comparable between both the intervention and usual care cohorts. Because we could not reliably estimate the differential program costs associated with the structured intervention used by Sun, et al., we have taken previously published costs developed from the lifestyle intervention of the Diabetes Prevention Program (DPP), which we assume to be greater than those that would be incurred by reproducing the conditions of Sun, et al.[18] We believe this to be a conservative assumption. Included in the structured intervention costs are training courses, testing, group sessions, in-person visits, phone calls and supervised exercise sessions.[20]

To investigate the effects of smaller improvements in A1c, the mean A1c difference between cohorts was varied by 0.3% (7.0% compared to 6.7%) as reported by Tatti, et al.,[16] and 0.5% (7.8% compared to 7.3%), similar to results reported by Escalante, et al.[15] In these two scenario comparisons the program costs are equal because DSNMR was the only treatment difference between the intervention and control cohorts. In each scenario, DSNMR is considered: 1) as an "equal cost" meal replacement; that is, the DSNMR cost is the same as the cost of the meal it replaces and that the cost is borne by the patient; and 2) as an "additional cost" of $1.00 per day (this cost is an average retail price, excluding local sales tax, of the DSNMR product at three stores in San Antonio, Texas in June 2008).

Our second scenario type demonstrates the degree to which model results are sensitive to scenario assumptions. Our intent in the design of these experiments was to alter one variable effect at a time for the purpose of demonstration. For these comparisons, we removed the lifestyle program costs and utility from the scenarios in which we reproduce and extend the results reported by Sun, et al. in order to demonstrate the effect of program costs and utility on the results. This is not intended to suggest that the results (0.8% A1c improvement) reported by Sun, et al. are achievable by simply adding DSNMR to usual care. We then used that same scenario without the lifestyle program costs and utilities to show the effect of an alternative set of utility values. We subsequently included two sets of scenarios at alternative A1c levels to indicate how cost-effectiveness results might vary for patients with higher or lower levels of glycemia. For all scenarios where DSNMR is an added cost we alternatively show results that assume a 0% discount rate.

RESULTS

Model validation

Table 2 reports the results of the validation runs for the major microvascular and macrovascular complication pathways. Reference values are expressed as numbers of patients in each complicated (health) state and the model results are expressed as 95% confidence intervals (computed using the CONFIDENCE function in MS Excel (Microsoft Corp., Redmond, WA, USA)) around mean numbers of patients in each state. All reference values fall within the respective confidence interval.

Simulation scenarios

The results of the simulation scenarios are compared in Tables 3 and 4. Except in the scenarios where the DSNMR intervention is less costly and more effective (referred to as *dominant*), the results are presented as incremental cost effectiveness ratios (ICER) that reflect the additional cost an intervention incurs per QALY gained.

Table 2. Model validation results

Disease State	Reference Value (Patients)†	Model Value (Patients)‡	Mean A1c Level (%)	Reference
Retinopathy	470	463.2-474.4	7.0	1
	820	812.6-821.4	9.3	1
Nephropathy	104	100.8-108.0	7.0	2
	273	269.5-279.9	9.3	2
Neuropathy	115	110.1-117.3	7.0	2
	235	234.6-243.8	9.3	2
Myocardial infarction	167	156.7-169.9	7.0	2
	216	203.0-217.8	9.3	2
Stroke	58	54.0-58.8	7.0	2
	58	53.3-58.5	9.3	2

†Reference values computed using published incidence rates to determine the number of patients in a 1,000 patient cohort who would develop the complication in the time period indicated in the reference and at the specified mean A1c level.
‡Model values are expressed as 95% confidence intervals (computed using the CONFIDENCE function in MS Excel) on the same number of patients and under the same conditions as the reference values.

Table 3. Cost effectiveness in drug-naïve patients with type 2 diabetes in scenarios that extend the results of clinical trials

Number	Scenario Conditions	ICER ($)† (3% Discount Rate)	ICER ($)‡ (3% Discount Rate)	ICER ($)‡ (0% Discount Rate)
1	Usual care (A1c: 7.8%) compared to DSNMR + Structured Lifestyle Intervention Program (A1c: 7.0) (0.8% difference)	34,979	47,917	45,942
2	Usual care (A1c: 7.0%) to DSNMR intervention (A1c: 6.7%) (0.3% difference)	DSNMR Dominant	55,036	50,315
3	Usual care (A1c: 7.8%) to DSNMR intervention (A1c: 7.3%) (0.5% difference)	DSNMR Dominant	50,414	44,935

ICER: Incremental Cost-effectiveness Ratio (cost per quality adjusted life year gained).
†Scenarios with DSNMR as an equal value (i.e., no additional cost) meal replacement.
‡Scenarios with DSNMR as an added cost meal replacement.

In comparison, usual care is compared to an intervention where the DSNMR is integrated into a structured lifestyle intervention. The ICER of the DSNMR lifestyle intervention is $34,979-$47,917 per QALY gained, depending on whether the DSNMR is considered an equal value or added cost meal replacement. The roughly $13,000 difference in ICER as a result of adding the DSNMR product cost reflects the relatively small difference in discounted QALY between the cohorts over the 10 year simulated period.

In comparisons 2 and 3, when the DSNMR is considered an equal value meal replacement, the DSNMR intervention *dominates* usual care; that is, the total costs are lower and utilities are greater for the DSNMR intervention. In these two scenarios, the program costs are essentially the same and the overall cost reduction is attributed to lower direct medical costs for the DSNMR cohort due to the lower incidence and later onset of complications. When the DSNMR intervention is considered to be an additional cost meal replacement, the ICER of the DSNMR intervention ranges from $50,414 per QALY gained to $55,036 depending on the improvement in A1c.

Sensitivity analysis

The purpose of these analyses (Table 4) is to test the sensitivity of the simulation results to our assumptions about lifestyle program costs and utility, to an alternative set of utility values[21], and to alternative levels of A1c (7.0% vs 6.2%; and 9.3% vs 8.5%, usual care vs DSNMR, respectively). All of the scenarios for the sensitivity analysis are

Table 4. Sensitivity analysis results

Number	Conditions	ICER ($)† (3% Discount Rate)	ICER ($)† (0% Discount Rate)
4	Usual care (A1c: 7.8%) compared to DSNMR intervention (A1c: 7.0%) (0.8% difference)	27,957	25,172
5	Usual care (A1c: 7.8%) compared to DSNMR intervention (A1c: 7.0%); alternative utility values	30,599	27,460
6	Usual care (A1c: 7.0%) compared to DSNMR intervention (A1c: 6.2%) (0.8% difference)	30,718	27,853
7	Usual care (A1c: 9.3%) compared to DSNMR intervention (A1c: 8.5%) (0.8% difference)	46,807	43,321

ICER: Incremental Cost-effectiveness Ratio (cost per quality adjusted life year gained).
†Scenarios with DSNMR as an added cost meal replacement.

variants of scenario 1 in which usual care (characterized in the model by mean A1c of 7.8%) is compared to a DSNMR structured lifestyle intervention (with mean A1c of 7.0%). Our purpose in selecting scenario 1 as the basis for comparison, with an A1c difference of 0.8%, was to be able to show the reduction in the ICER when program costs and utility are removed, as in Comparison 4. We continued the sensitivity analysis using scenarios with a 0.8% difference in A1c to provide a consistent basis for comparison. Use of these scenarios is not intended to imply that use of DSNMR alone would result in a 0.8% reduction in A1c, and we have found no evidence that such an assertion would be valid.

When alternative utility values are used in the scenarios in comparison 5, the ICER of the DSNMR intervention is comparable to that of comparison 4, which indicates nominal sensitivity of the results to assumptions about utility values. Comparisons 6 and 7, which vary in terms of A1c levels but retain a 0.8% difference between cohorts, indicate that an optimum cost-effectiveness point may exist at A1c levels similar to those in comparison 4. The comparison of these scenarios indicates that at the lowest levels of A1c (7.0% and 6.2%), the patients of both cohorts remain relatively healthy with smaller relative differences in both direct medical costs and QALY, and the product cost of the DSNMR intervention becomes more significant. Conversely, at the higher levels of A1c (9.3% and 8.5%), both groups experience greater incidence of complications and the increased direct medical costs as a result of those complications result in a higher cost for relatively small differences in QALY.

DISCUSSION

Although the available data reviewed suggest that MNT is cost-effective in diabetes management,[9,22] this is the first study reporting specific cost analysis for DSNMR. Our intent has been to present a series of comparisons of DSNMR interventions to traditional therapy regimens under varying cost and effectiveness conditions. Our analysis suggests that DSNMR provides a long-term clinical benefit at a somewhat higher cost - ranging between $35,000 and $55,000 per QALY-compared to usual care. In comparison with many other well-accepted health interventions, the specific DSNMR interventions included in this analysis are highly cost-effective.[23]

An integrated approach to diabetes management including patient education, attention to diet, lifestyle, self-monitoring of blood glucose, medications and close follow-up is considered critical to helping patients with diabetes achieve and maintain adequate glucose control to prevent costly complications. The American Diabetes Association and other organizations support medical nutrition therapy as standard of care for managing diabetes and preventing or at least slowing the rate of development of diabetes complications.[12] Although no single nutritional intervention works to treat all people with diabetes, foods and nutrition interventions that reduce postprandial blood glucose excursions are important to manage the disease. Diabetes educators are encouraged to motivate people using tailored nutrition strategies, including meal replacements if appropriate.[12] This analysis shows that including DSNMR is also a cost-effective part of the diabetes management plan.

It is challenging to separate the effects of individual components of diabetes lifestyle interventions due to the nature of the interventions which are often part of more extensive medical care;[22] accordingly, a number of assumptions inherent in this analysis must be considered. First, although compliance is an important consideration, we have ignored these differences, assuming patients are at least as compliant as those in the clinical trials which are the basis for our model. Some may argue that adherence to lifestyle interventions may be difficult over the long-term; however, sufficient evidence exists that indicate compliance to diabetes medication (including both oral and insulin) also is suboptimal.[24] Further, we assume that the results published from the clinical trials can be duplicated in the general population of patients newly diagnosed with type 2 diabetes, and that the correlation of A1c levels to risks for diabetes-related complications is consistent across populations. This particular assumption is important to these results because the model is based on trial data from Europe, Asia, and North America.

Our modeling approach focusing on A1c may ignore additional effects, either positive or negative, that result from targeting postprandial glucose with a dietary intervention.[7] We have not attempted to integrate the effects of weight loss on general well being or on complications risks, nor have we attempted to account for beneficial effects on blood pressure or lipids. Ignoring these biases our results against DSNMR. Conversely, we have not applied any negative (or positive) utility effects to reflect patient preferences for usual food compared to DSNMR, and this could possibly bias our results. Finally, we have tied this economic analysis and assumptions to published trial data where possible and reasonable so they would contribute to a conservative estimate of the cost-effectiveness of a DSNMR intervention.

In summary, these results illustrate that including a DSNMR as part of a lifestyle intervention that results in improved metabolic control can be cost effective over the long-term. Clearly, long-term trials must be conducted to validate this model. One such study is in progress: the 12 year Look AHEAD trial,[25] designed to compare effects of a lifestyle intervention including meal replacements such as DSNMR with a standardized program of diabetes education and support, will contribute to our understanding of the economic advantage of lifestyle intervention and medical nutrition therapy on long-term outcomes in type 2 diabetes.

AUTHOR DISCLOSURES

All authors declared there is no conflict of interest.

REFERENCES

1. Klein R, Klien B, Moss S. Relation of glycemic control to diabetic microvascular complication in diabetes mellitus. Ann Intern Med. 1996;124:90-6.
2. UK Prospective Diabetes Study (UKPDS) Group. Intensive blood-glucose control with sulphonylureas or insulin compared with conventional treatment and risk complications in patients with type 2 diabetes (UKPDS 33). Lancet. 1998; 352:837-53.

3. ADVANCE Collaborative Group. Intensive blood glucose control and vascular outcomes in patients with type 2 diabetes. N Engl J Med. 2008;358:2560-72.
4. Action to Control Cardiovascular Risk in Diabetes (ACCORD) Study Group. Effects of intensive glucose lowering in type 2 diabetes. N Engl J Med. 2008;358:2545-59.
5. Holman R, Paul S, Bethel M, Matthews D, Neil A. 10-Year follow-up of intensive glucose control in type 2 diabetes. N Engl J Med. 2008;359:1577-89.
6. Monnier L, Lapinski H, Colette C. Contributions of fasting and postprandial plasma glucose increments to the overall diurnal hyperglycemia of type 2 diabetic patients. Diabetes Care. 2003;26:881-5.
7. Beisswenger P, Heine RJ, Leiter LA, Moses A, Tuomilehto J. Prandial Glucose Regulation in the Glu ose Triad. Emerging Evidence and Insights. Endocrine. 2004;25;195-202.
8. Pastors J, Franz M, Warshaw H, Kulkarni K, Daly A. The Evidence for the Effectiveness of Medical Nutrition Therapy in Diabetes Management. Diabetes Care. 2002;25:608-13.
9. American Dietetic Association: ADA's definition for nutrition screening and nutrition assessment. J Am Diet Assoc. 1994;94:838-9.
10. Elia M, Ceriello A, Laube H, Sinclair A, Enfger M, Stratton R. Enteral nutritional support and use of diabetes-specific formulas for patients with diabetes. Diabetes Care. 2005;28: 2267-79.
11. The Look AHEAD Research Group. Reduction in Weight and Cardiovascular Disease Risk Factors in Individuals with Type 2 Diabetes. Diabetes Care. 2007;30:1374-83.
12. American Diabetes Association. Nutrition Recommendations and Interventions for Diabetes, A Position Statement of the American Diabetes Association. Diabetes Care. 2008; 31:S61-S78.
13. Fix GM, Lowe W, Cockram DB, Craig LD. Effect of a liquid nutritional supplement containing a novel carbohydrate system on glucose tolerance in subjects with type 2 diabetes. Ann Nutr Metab. 2001;45(S1):277.
14. Sun J, Wang Y, Chen X, Chen Y, Feng Y, Zhang X et al. An integrated intervention program to control diabetes in overweight Chinese women and men with type 2 diabetes. Asia Pac J Clin Nutr. 2008;17:514-24.
15. Escalante-Pulido M, Milke-Najar M, Rodriguez-Lopez E, Ambrosio-Macias K, Torres A. Clinical and metabolic effects of liquid nutrition meal replacement plan vs. individualized diet plan in obese childhood subjects with type 2 diabetes mellitus (Abstract). Presented at the International Diabetes Federation Congress, 2007.
16. Tatti P, Di Mauro P. Effect of a low calorie high nutritional value formula on weight loss in type 2 Diabetes mellitus. Mediterr J Nutr Metab. (in press)
17. O'Brien J,Patrick A, Caro J. Estimates of direct medical costs for microvascular and macrovascular complications resulting from type 2 diabetes mellitus in the United States in 2000. Clin Ther. 2003;25:1017-38.
18. Herman W, Hoerger T, Brandle M, Hicks K, Sorenson S, Zhang P, Hamman R, Ackermann R, Engelgau M, Ratner R. The cost-effectiveness of lifestyle modification or metformin in preventing type 2 diabetes in adults with impaired glucose tolerance. Ann Intern Med. 2005;142:323-32.
19. Coffey J, Brandle M, Zhou H, Marriott D, Burke R, Tabael B, Engelgau M, Kaplan R, Herman W. Valuing health-related quality of life in diabetes. Diabetes Care. 2002;25: 2238-43.
20. Diabetes Prevention Program Research Group. Reduction in the incidence of type 2 diabetes with lifestyle intervention or metformin. N Engl J Med. 2002;346:393-403.
21. Clarke P, Gray A, Holman R. Estimating utility values for health states of type 2 diabetic patients using the EQ-5D (UKPDS 62). Med Decis Making. 2002;22:340-9.
22. Urbanski P, Wolf A, Herman W. Cost-effectiveness of Diabetic Education. J Am Diet Assoc.2008;108:S6-S11.
23. Russell L. Preventing chronic disease: an important investment, but don't count on cost savings. Health Affairs. 2009; 28:42-5.
24. Cramer J. A Systematic Review of Adherence With Medications for Diabetes. Diabetes Care. 2004;27:1218-24.
25. Delahanty L, Nathan D. Implications of the Diabetes Prevention Program and Look AHEAD Clinical Trials for Lifestyle Interventions. J Am Diet Assoc. 2008;108:S66-S72.

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糖尿病专用营养配方的經濟效益分析

本文透过比较结构性干预管理方案与常规治疗方案对糖尿病患者 10 年治疗效果与医疗费用的差别，研究一种糖尿病患专用营养配方对糖尿病营养治疗的效用。利用现有的临床试验数据，我们研发了一个计算机模拟程式以追踪糖尿病患者微血管和大血管的健康状况、累计医疗费用和生活质量调整的生命年限。这一模拟程式能够建立及比较各种生活方式。当糖尿病专用营养配方的使用是实验组与对照组的唯一差别，在其他开支相同的情况下，糖尿病专用营养配方干预措施成本更低，比常规治疗更加有效。当其作为额外的代餐，根据糖化血红蛋白的改善情况，糖尿病专用营养配方能增加成本效益比 50,414 到 55,036 美元。假如将糖尿病专用营养配方用于糖尿病结构性干预管理方案中，则能提高成本效益比 47,917 美元。综上所述，本研究发现使用糖尿病专用营养配方在各种模拟的方式下皆能提高成本效益。

關鍵字：营养治療、第二型糖尿病、计算机模擬、成本分析、生活质量调整的生命年限