Diabetes, Metabolic Syndrome and Obesity: Targets and Therapy

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REVIEW

Success of nutrition-therapy interventions in persons with type 2 diabetes: challenges and future directions

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Marion J Franz[1]
Janice MacLeod[2]

[1]Nutrition Concepts by Franz, Minneapolis, MN, [2]Clinical Innovation, WellDoc, Columbia, MD, USA

Abstract: A systematic review was conducted by the Academy of Nutrition and Dietetics to determine the evidence for the effectiveness of individualized nutrition therapy provided by a dietitian nutritionist and evidence-based (EB) nutrition-therapy interventions in adults with diabetes. This article briefly reviews the systematic process used and summarizes the effectiveness evidence and intervention recommendations. In persons with type 2 diabetes (T2D), 18 studies met study criteria for the effectiveness question. A 0.3%–2.0% decrease from baseline in glycated hemoglobin was reported at 3 months in 13 study arms, a 0.3%–1.8% decrease at 6 months in 12 study arms, a 0.3%–1.6% decrease at 12 months with ongoing support in six study arms, and a 0.6%–1.8% decrease at >12 months in four study arms. An initial series of encounters with follow-up visits and implementation of a variety of nutrition-therapy interventions, all of which reduced energy intake, were reported. Nutrition therapy also significantly decreased doses or number of glucose-lowering medications used and resulted in improvements in quality of life. Mixed effects on cardiovascular risk factors and body weight were reported. Fourteen questions were identified related to nutrition-therapy interventions. A total of 38 studies met study criteria for the nutrition-intervention questions, from which 30 conclusion statements and 19 nutrition-practice guideline recommendations for T2D were written. Three additional NPG recommendations for T2D were written based on evidence reviewed by the American Diabetes Association. The 22 nutrition-intervention recommendations for T2D are summarized. How to implement nutrition-practice guideline recommendations effectively by health care providers and individuals with T2D remains challenging. Of importance, it is recognized that identifying and integrating EB digital health-technology tools into clinical practice are major challenges for future management of diabetes, self-management education, and support.

Keywords: nutrition therapy, dietitian nutritionists, systematic review, effectiveness, interventions, implementation, technology

Introduction

Nutrition-therapy interventions for persons with type 2 diabetes (T2D) must be individualized. However, as is imperative for all medical interventions, nutrition-therapy interventions, although individualized, must be evidence-based (EB). Dietitian nutritionists bring clinical expertise and experience, as well as knowledge of the evidence. The individual with diabetes brings his/her expertise in themselves and their lives. Dietitian nutritionists collaborate with them to make decisions about their nutrition-care plan, including food choices that fit with their lives. This information is shared with the health care team (HCT). Unfortunately, there can be a tendency for HCT members

Correspondence: Marion J Franz
Nutrition Concepts by Franz, 6635 Limerick Drive, Minneapolis, MN 55439, USA
Tel +1 952 996 0434
Fax +1 952 941 6734
Email MarionFranz@aol.com

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to make recommendations based on small, short-term studies or on proposed or suggested theories.[1] This may be due to trying to implement interventions that are more "dramatic" and "sensational" than EB interventions that they assume individuals have already tried to implement with little or no success.

To implement individualized, EB nutrition therapy for persons with T2D, it is important that the HCT first knows what nutrition-therapy interventions have been shown to be effective and be familiar with current research supporting EB nutrition-therapy interventions. The Academy of Nutrition and Dietetics (Academy) and the American Diabetes Association (ADA) have both published EB nutrition-therapy recommendations.[2–4] The Academy's nutrition guideline for T1D and T2D diabetes in adults was published in 2017.[2,3] Because it is the most recently published systematic review of evidence for the effectiveness of nutrition therapy for T2D and nutrition-therapy intervention recommendations, it is reviewed in this article. The ADA is in the process of updating their recommendations.

The Academy uses a five-step process for conducting systematic reviews and developing EB nutrition-practice guidelines (EBNPGs): write evidence-analysis questions, gather studies based on study-inclusion criteria, evaluate each article, summarize the evidence, and write conclusion statements. Based on evidence reviews and conclusion statements, EBNPGs are written and published in the Academy's Evidence Analysis Library.[5]

Study-inclusion criteria for the diabetes EBNPGs were being written in English, adults aged ≥18 years with T1D or T2D, outpatient and ambulatory care, randomized controlled trials, cohort studies, nonrandomized clinical studies, observational studies, study duration of at least 12 weeks, ten or more subjects per study group, and 80% completion rate. In addition to these criteria, studies on effectiveness of diabetes nutrition therapy had also to have documented that an individualized intervention was provided by a registered dietitian nutritionist (RDN). Sixty studies met inclusion criteria, 22 were related to effectiveness of nutrition therapy provided by RDNs (18 in T2D), and 38 were related to diabetes-nutrition interventions. All the studies are listed in Franz et al.[2] Although published systematic reviews are often used to write EBNPGs, there can be limitations with them that readers need to be aware of. First, inappropriate study-inclusion criteria may have been used. An example is a Cochrane Review on the value and use of low glycemic index (GI) diets for diabetes.[6] One criterion was to exclude studies in which subjects' diabetes was already optimally controlled. This is unusual: studies may be excluded because subjects are in very poor glycemic control, but rarely (if ever) because their control is too good. By doing this, the review excluded Wolever et al, in which high-carbohydrate (CHO)–high-GI, high-CHO–low-GI, and low-CHO–high-monounsaturated-fat diets were compared and no significant differences in glycated hemoglobin (HbA1c) found at 1 year. The study was excluded because of subjects' (n=162, T2D) good glycemic control (HbA1c ~6.1% at baseline).[7] By successfully eliminating this study, the review was able to conclude that "HbA1c decreased by 0.5% with low GI diets, statistically and clinically significant".[6] Second, studies may be included that are too short in duration, not taking into account that diabetes is a lifelong problem and requires long-term lifestyle changes.

Third, by requiring low dropout rates, studies may be eliminated where the intervention is too difficult for subjects to maintain long-term. An example is a study asking if low-CHO (<30 g/d) diets achieved in short-term, high-intensity intervention studies compare to low-fat diets and whether they can be achieved long-term (24 months) with lower-intensity interventions.[8] At 12 months in this study, only 53% of the subjects returned for the assessment visit, and at 24 months, 47%. At 3 months, the diets of subjects in the low-CHO group contained 24% CHO, at 5 months 40% CHO (back to baseline),and at 24 months 48% CHO. The researchers suggested the high dropout rate was because "low-carbohydrate diets may be difficult to sustain".[8] Furthermore, studies rarely ask the question if outcomes achieved from their studies can be implemented long-term with "real-world" eating. This is particularly important when determining nutrition-therapy interventions for a lifelong condition, such as T2D. However, even with these limitations, systematic reviews (and meta-analyses) remain today's best option for reviewing research.

Effectiveness of nutrition therapy in persons with T2D

The primary effectiveness question asked to develop the Academy's EBNPGs was: How effective is individualized nutrition therapy provided by a dietitian nutritionist over more than one visit on glycemia, cardiovascular disease (CVD) risk factors (lipids and blood pressure), weight management, medication usage, and quality of life? Secondary questions were: How many encounters are needed for implementation of effective nutrition therapy? and What type of nutrition-therapy interventions (in clinical practice) are effective? Study-inclusion criteria are listed in the previous section.

To answer the effectiveness questions in persons with T2D, 18 studies (n=4,181) met study criteria. A 0.3%–2.0% decrease in HbA1c at 3 months was reported in 13 study arms, a 0.3%–1.8% decrease at 6 months in 12 study arms, a 0.3%–1.6% decrease at 12 months with ongoing support, and a 0.6%–1.8% decrease at >12 months in four study arms.[2] These outcomes are similar to those from oral glucose-lowering medications. Although nutrition therapy was effective throughout the disease process, decreases were largest in newly diagnosed persons and/or persons with baseline HbA1c >8.0% (0.5%–2.0%). Nutrition therapy was compared to usual care in six studies, with the usual-care arms reporting a 0–0.2% increase in HbA1c.

In 16 studies in persons with T2D, nutrition therapy had mixed effects on CVD risk factors in persons with normal or mildly elevated lipid levels (total cholesterol, low-density-lipoprotein cholesterol, triglycerides) and normal to mildly low high-density-lipoprotein cholesterol and in persons with near-normal blood pressure. Furthermore, 50%–75% of persons were on lipid-lowering or antihypertensive medications. In 16 studies in persons with T2D, nutrition therapy also had mixed effects on body weight: ten studies reported decreases of 2.4–6.2 kg and four studies reported insignificant weight outcomes.

In eleven studies in persons with T2D, nutrition therapy significantly decreased doses or number of glucose-lowering medications used. Weight gain with initiation of insulin therapy was also prevented. Three studies in persons with T2D in whom nutrition therapy was implemented reported statistically significant improvements in quality of life (improved self-perception of health status, increased knowledge and motivation, and decreased emotional stress).

Initial series of dietitian/nutritionist encounters (during the first 3–6 months) were a minimum of three, ranging from three to 12 encounters. Follow-up visits (during the next 6–15 months) were a minimum of 2 hours, ranging 2–16 hours. Follow-up encounters during the next 6–15 months were a minimum of 1 hour and ranged 1–6 hours. A variety of nutrition-therapy interventions, such as individualized nutrition therapy, energy restriction, portion control, sample menus, CHO counting, exchange lists, simple meal plans, and low-fat vegan diets, were implemented and effective. All nutrition-therapy interventions for persons with T2D resulted in reduced energy intake. Furthermore, outcomes of nutrition therapy on HbA1c were known by 6 weeks to 3 months, at which time the dietitian/nutritionist assessed if therapy goals had been met by lifestyle changes or if changes/additions in medications were needed.

Based on the systematic review of the evidence for nutrition-therapy effectiveness, the Academy NPGs recommend the following for adults with T2D:[2]

- dietitian nutritionists implement three to six encounters during the first 6 months and then determine whether additional encounters are needed;
- a minimum of one annual follow-up encounter;
- individualize nutrition-therapy interventions with a focus on reduced energy intake, and implement in collaboration with the adult with diabetes;
- personal preferences (eg, tradition, culture, religion, health beliefs and goals, and economics) and metabolic goals should be considered when recommending one eating pattern over another;
- treatment decisions should be based on EB recommendations that are tailored to the individual's preferences, prognoses, and comorbidities.

Nutrition-therapy interventions

Fourteen questions were identified related to nutrition-therapy interventions for adults with diabetes.[3] A total of 38 primary studies (33 randomized controlled trials, 4 observational, and 1 systematic review) were analyzed. From the review, 30 conclusion statements and 19 NPG recommendations for T2D were developed. Three additional NPG recommendations for T2D were developed based on evidence reviewed by the ADA.[4,9] The 22 NPG recommendations for nutrition interventions for T2D are summarized in Table 1.[2,3]

Challenges and future directions

Challenges for both the individual with T2D and HCT continue to be how to implement EBNPG interventions effectively. HCT members may continue to focus on weight loss as their primary recommendation to persons with T2D.[10] If individuals would just lose weight, the problem would be solved. It sounds so simple, yet anyone dealing with weight loss and maintenance issues realizes it is not that simple. The cycle of less weight loss than expected or wanted and subsequent weight regain continues, despite individuals' best efforts.[1] A major challenge is updating HCTs on the role of weight management across the continuum of obesity to prediabetes to diabetes[11] and the complex biological mechanisms that make weight-loss maintenance difficult.[12–15] As noted, a major lifestyle factor for successful glycemic outcomes is reduced energy intake, not necessarily weight loss. For some, reduced energy intake may lead to weight loss, for some it

Table 1 Academy of Nutrition Dietetics nutrition-practice guideline for T2D: intervention recommendations

Energy intake
- For overweight or obese adults with T2D, encourage a reduced energy, healthy eating plan with a goal of weight loss, weight maintenance, and/or prevention of weight gain.
- For appropriate-weight adults with T2D, encourage consumption of a healthy eating plan with goals of weight maintenance and/or prevention of weight gain.

Macronutrient composition
- In collaboration with the adult with T2D, individualize the macronutrient composition of a healthy eating plan within appropriate energy intake.

Carbohydrate management strategies

For adults on nutrition therapy alone or taking other diabetes medications (other than insulin secretagogues)
- Educate based on abilities, preferences, and management goals on one of the following:
- carbohydrate counting alone;
- plate method, portion control, simplified meal plan;
- food lists and carbohydrate choices.

For adults using fixed insulin doses or insulin secretagogues
- Educate based on abilities, preferences, and management goals on carbohydrate consistency (timing and amount) using one of the carbohydrate-management strategies listed above.

For adults with T2D using multiple daily insulin injections or insulin-pump therapy
- Educate adults on carbohydrate counting using insulin:carbohydrate ratios based on abilities, preferences, and management goals.

Fiber intake
- Encourage consumption of dietary fiber from fruit, vegetables, whole grains, and legumes at levels recommended by Dietary Reference Intakes (21–25 g/day for adult women and 30–38 g/day for adult men, depending on age) or US Department of Agriculture (14 g fiber per 1,000 kcal) due to the overall health benefits of dietary fiber.

Glycemic index (GI) and glycemic load (GL)
- If GI or GL is proposed as a glycemia-lowering strategy, advise that lowering GI or GL may or may not have a significant effect on glycemic control. Studies longer than 12 weeks report no significant influence of GI or GL, independent of weight loss, on HbA1c levels.

Nutritive sweeteners
- Educate that intake of nutritive sweeteners when substituted isocalorically for other carbohydrates will not have a significant effect on HbA1c or insulin levels.
- Advise against excessive intake of nutritive sweeteners to avoid displacing nutrient-dense foods and to avoid excessive calories and carbohydrate intake.

Nonnutritive sweeteners
- Educate that intake of FDA-approved nonnutritive sweeteners (such as aspartame, sucralose, and steviol glycosides) within the acceptable daily intake levels established by the FDA will not have a significant influence on glycemic control.
- Educate that substituting foods and beverages containing FDA-approved nonnutritive sweeteners within the recommended daily-intake levels established by the FDA can reduce overall calories and carbohydrate intake; however, other sources of calories and carbohydrates in these foods and beverages need to be considered.

(*Continued*)

Table 1 (*Continued*)

Protein intake and protein intake for diabetic kidney disease (DKD)
- Educate that adding protein to meals and/or snacks does not prevent or assist in the treatment of hypoglycemia. Ingested protein appears to increase insulin response without increasing plasma-glucose concentrations.
- Educate adults with diabetes and DKD that protein restriction does not have a beneficial effect on glomerular filtration rate (GFR).
- Educate adults with T2D and DKD that the type of protein (vegetable-based vs animal-based) will not have a significant effect on GFR.

Cardioprotective eating patterns
- Encourage a cardioprotective eating pattern within the recommended energy intake.
- Encourage an individualized reduction in sodium intake. The recommendation for the general public to reduce sodium to <2,300 mg/day is also appropriate for adults with diabetes; for adults with diabetes and hypertension, further reductions in sodium intake should be individualized.

Vitamin, mineral, and/or herbal supplementation
- If vitamin, mineral, and/or herbal supplementation is proposed as a diabetes-management strategy, advise there is no clear evidence from supplementation in people who do not have underlying deficiencies.

Alcohol consumption[a]
- Advise and educate adults that when they choose to drink alcohol, they should do so in moderation (up to one drink per day for adult women and up to two drinks per day for adult men; one drink is equal to 350 mL beer, 150 mL wine, or 45 mL distilled spirits). Alcohol consumption may place adults at increased risk of delayed hypoglycemia when using insulin or insulin secretagogues.

Physical activity[a]
- Encourage an individualized physical activity plan, unless medically contraindicated, to gradually achieve the following:
- accumulating 150 minutes or more of physical activity per week;
- moderate-intensity aerobic exercise (50%–70% maximum heart rate) spread over at least 3 days per week, with no more than 2 consecutive days without exercise;
- resistance training at least twice per week;
- reduce sedentary time by breaking up extended amount of time (>90 minutes) spent sitting.
- Educate adults taking insulin or insulin secretagogues that physical activity may cause hypoglycemia in cases where medication doses or carbohydrate consumption is not altered.

Glucose monitoring[a]
- Ensure that adults with T2D are educated about glucose monitoring and using data to adjust therapy.

Notes: [a]Recommendations based on American Diabetes Association recommendations.[4,9] Adapted from Franz MJ, MacLeod J, Evert A, et al. Academy of Nutrition and Dietetics nutrition practice guideline for type 1 and type 2 diabetes in adults: systematic review of evidence for medical nutrition therapy effectiveness and recommendations for integration into the nutrition care process. *J Acad Nutr Diet*. 2017;117:1659–1679. Available from: https://jandonline.org/article/S2212-2672(17)30332-5/pdf.[2] Data from MacLeod et al.[3]

Abbreviations: T2D, type 2 diabetes; HbA1c, glycated hemoglobin; FDA, Food and Drug Administration.

may assist with weight-loss maintenance, and for some it may prevent weight gain.[16] However, it is a major challenge for individuals with T2D to maintain a reduced-energy healthy eating pattern. Adding the importance of regular physical activity adds to the challenge.[17]

The HCT may also implement interventions based on short-term studies or theories, perhaps hoping the "new" interventions will be easier for persons with T2D to implement or at the very least are something "new" to try. An early example was dietary fiber recommendations. Short-term, small-sample studies on consumption of very large amounts of fiber (44–50 g fiber daily) reported improvement in glycemia. However, studies using more usual intake (up to 24 g/day) reported little or no improvement in glycemia and CVD risk markers.[18] Another example is the GI. Early short-term studies seemed promising, but larger longer-term studies reported the variability in GI responses from CHO-containing foods within and among individuals.[19] Furthermore, most individuals with diabetes appear to consume a moderate-GI diet, and it is unclear whether reducing the usual GI in the diet by a few units will meaningfully improve glycemic control.[18]

More recently, low-CHO diets have become popular. As noted in the introduction, research providing very intense interventions showed benefit from low-CHO diets, but when these diets were recommended using implementations more feasible for clinical practice, they were difficult for persons with T2D to implement long-term and did not lead to favorable glycemic outcomes.[8] A recent review examined the effectiveness of low-CHO diets in persons with T2D.[20] Nine previous meta-analyses incorporating 153 studies were identified. Five reported improved glycemia with low-CHO diets and four reported no differences between low-CHO and higher-CHO diets on glycemia. To improve the quality of the studies analyzed, the following criteria were used: randomized controlled trials >4 weeks, CHO intake ≤45% of total energy intake, and dietary assessment at the end of the study. Twelve studies met inclusion criteria and reported no significant differences in metabolic markers, including glycemia, between the two diets. This review noted the variable quality of studies in the earlier meta-analyses likely explained the inconsistent findings among meta-analyses.

As shown in the evidence review,[2] there is support for the idea that total energy intake of an eating pattern outweighs the distribution of CHO in terms of importance. Furthermore, individuals with T2D do not have low- or high-CHO intake, but rather report a moderate intake of ~45% of total caloric intake.[21] It also appears difficult for people with T2D to eat a high-CHO diet. In a prospective UK study, despite receiving individual education from dietitians on the recommended CHO intake of 50%–55%, people with T2D reported a CHO intake of 43% energy intake, which was similar to the general public.[22] It is further estimated that people with diabetes consume approximately 36%–40% of their calories from fat and 16%–18% from protein.[23] It would thus seem prudent to recommend an eating pattern with moderate amounts of CHO that is low in saturated fats and includes fruits, vegetables, whole grains, and low-fat dairy foods in appropriate amounts and portion sizes.[4] How best to educate the HCT and facilitate behavior changes in persons with T2D remain active areas of needed research.

Identifying and integrating EB digital health technology into clinical practice will be critical in the future management of diabetes, self-management education, and support (DSMES). To be effective, proven technology must become integral to future diabetes management and DSMES. Digital health technology, often referred to as "eHealth", provides the critical platform for access, reach, and efficiency to improve patient experience of care and the health of populations, while reducing the per capita cost of health care.[24] Digital health tools make it possible for patients to be at the center of their care by providing anytime, anywhere individualized ongoing support. The resulting patient-generated data are able to be shared with the HCT, informing timely care-plan adjustments. The challenge to the HCT is how they can adapt their workflow and practices best to partner with the new "e-patient" (educated, empowered, and engaged).[25] The challenge to dietitian nutritionists and diabetes educators is how best to integrate virtual DSMES with medical management and how to embed it at the point of care, with the goal being to improve access, clinical outcomes, and cost-effectiveness.

Summary

The evidence is strong that nutrition therapy provided by dietitian nutritionists is effective and essential in the management of diabetes. However, EB nutrition-therapy interventions must be individualized and implemented in collaboration with the adult with diabetes. Personal preferences (eg, tradition, culture, religion, health beliefs, goals, and economics) must be considered when recommending eating patterns. Furthermore, outcomes must be monitored and evaluated to determine if treatment goals are being met or if a change in overall therapy (medication) is needed. The challenge is how best to educate the HCT and persons with diabetes to implement EB diabetes nutrition-therapy interventions into clinical medical practice and for the self-management of diabetes. A major challenge for HCTs and educators is the acceptance, integration, and implementation of digital health technology.

Disclosure

The authors report no conflicts of interest in this work.

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