

# Dietary Treatment of Diabetes

A Systematic Review

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# Summary and Conclusions of the SBU Report: Dietary Treatment of Diabetes

## A Systematic Review

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# SBU's Conclusions

- In type 2 diabetes, low-fat and moderate low-carbohydrate diets (30–40% of the energy from carbohydrates) have similar, favorable effects on HbA<sub>1c</sub> (long-term blood glucose) and body-weight. The absence of sufficient-quality studies in people with diabetes prevents evaluation of the long-term effects of more extreme diets involving low-carbohydrate and high-fat intake, eg, so-called “low-carb, high-fat” (LCHF) diets. Hence, safety aspects become particularly important in clinical follow-up of individuals who choose extreme low-carbohydrate diets (10–20% energy from carbohydrates).
- Limited scientific evidence shows that vegetables, legumes, and fish are beneficial for people with diabetes. These foods are important components of the current dietary recommendations in diabetes. The literature review did not reveal evidence for drawing conclusions on other key components of dietary recommendations, eg, whole grain products and fat content. No scientific evidence has emerged either for or against changing the current dietary recommendations in diabetes.
- People with type 2 diabetes who regularly consume moderate amounts of alcohol have a lower morbidity and mortality from cardiovascular disease than do people who consume no alcohol. Obviously, advice on using alcohol must take into consideration pregnancy or the risk of alcohol abuse. People who drink coffee have a lower risk of cardiovascular disease than those who do not drink coffee.

- So-called “lifestyle intervention”, which combines advice for low-fat, high-fiber diets and increased physical activity, protects against the development of diabetes in people with impaired ability to manage and metabolize glucose (impaired glucose tolerance).
- The absence of sufficient-quality studies prevents evaluation of the importance of the distribution of nutritional intake, or the intake of proteins and whole grain products, throughout the day (24 hours). Also absent are studies addressing the effects of diet on quality of life and on the incidence of eye and renal complications.
- Many studies are under way to evaluate different diets in diabetes. As the results of high-quality studies become available, the conclusions of this report may need to be revised.

# SBU's Summary

## Background and Aim

Health services have traditionally given dietary advice to people with diabetes. However, experts have often disagreed on the importance of diet in patient health and the most appropriate composition of diet. In 2004, the Diabetes and Nutrition Study Group of the European Association for the Study of Diabetes published its recommendations. In compliance with these recommendations, most Swedish dietitians, physicians, and nurses recommend that patients eat substantial quantities of vegetables, legumes, fish, and whole grain foods, that fat intake should consist of a high proportion of unsaturated fats and low proportion of saturated fats, and that the total energy intake should be adapted to the needs of the individual.

The application of such recommendations in diabetes is often questioned. During different periods the discussion has focused on the content of proteins, carbohydrates, and fats, on the distribution of different types of fats and carbohydrates, or on meal-time schedules. In recent years, the discussion in Sweden (largely inspired by the lively debate in the United States) has focused mainly on the amount and type of carbohydrates. Several new diets have been promoted concurrently. The ones receiving most

attention are diets involving a low glycemic index (GI) and foods extremely low in carbohydrates and high in fat (eg, Atkins or LCHF diet). Several of the new diets have been suggested as being particularly appropriate for people with diabetes.

Dietary advice within the framework of health services applies not only to people with diabetes, but also when impaired glucose tolerance or elevated fasting blood glucose is detected, eg, in association with pregnancy or diseases involving severe physical stress. Hence, our literature review has included studies of people with impaired glucose tolerance or elevated fasting blood glucose.

This project has aimed to use a systematic literature review to assess the scientific evidence underlying dietary recommendations for people with diabetes and impaired glucose tolerance or elevated fasting blood glucose. The objectives did not include a review of the literature on dietary counselling of healthy individuals as a means to prevent diabetes (ie, primary prevention).

The dietary components included in the review are proteins, fats, and carbohydrates – so-called “macronutrients” – fibers, and certain foods. We have not, however, reviewed the literature on specific dietary supplements or replacements, eg, protein powders or sweeteners. Since dietary counselling within the health services generally includes advice on various beverages, we have reviewed the scientific evidence for recommendations concerning the most common beverages.

The primary purpose of dietary counselling is to prevent the long-term complications of diabetes. This review does not cover the short-term (ie, days or weeks) effects of different diets.

## **Facts 1** Main dietary themes of the report.

Low-fat diets (maximum 30% of energy intake from fat)  
Low-carbohydrate diets (maximum 40% of energy intake from carbohydrates)  
Food and dietary patterns  
Beverages (alcohol, coffee, tea, milk, soft drinks, and juice)  
Dietary treatment combined with exercise

## **Method**

### **Systematic literature review**

The report is based on a systematic review of the scientific literature on the topic. The literature search covers the period from 1980 through September 2009, with the intent to identify all relevant scientific studies.

The systematic literature review has been limited to studies of the dietary content of foods, macronutrients (proteins, fats, and carbohydrates), fibers, and beverages in adults with diabetes, impaired glucose tolerance, or elevated fasting blood glucose. Studies were included if they had follow-up times of at least 1 year for diabetic complications and other primary endpoints and at least 24 weeks for laboratory values and weight, and had at least 50 participants with impaired glucose tolerance or diabetes in each group (studies with fewer participants were accepted only if they had been preceded by power analysis).

The review includes randomized clinical trials (RCTs) and observational studies. Observational studies had to be prospective, ie, a group of patients, after an initial survey, was followed forward in time.



In people with impaired glucose tolerance, studies addressing the risk of developing diabetes were reviewed. In people with diabetes, the primary endpoints concerned survival, risk of developing diabetic complications, and measurements of quality of life/well being. The effects of diet on weight, HbA<sub>1c</sub>, and other laboratory values were secondary endpoints in this review. The review also includes information on the percentage of trial participants who successfully adhered to the intended diet.

Studies were evaluated for quality by using validated templates on applicability to Swedish conditions (relevance) and study quality, both of which were graded as high, medium, or low.

The literature review complied with SBU's systematic methodology for searching databases for relevant literature. Each included study was appraised for quality and summarized in table format. The international GRADE system was used in the final assessment of the collective body of scientific evidence, upon which the conclusions of the report are based (Facts 2). Assessment of the overall strength of the evidence considers the following factors: study quality, consistency/concordance, transferability/relevance, data precision, risk of publication bias, effect size, and dose–response relationship.

## Facts 2 Study quality and strength of the evidence.

**Study quality** refers to the scientific quality of an individual study and its ability to provide a valid answer to a specific question.

**Strength of the evidence** refers to a judgment of the total strength of all scientific evidence and its ability to provide a valid answer to a specific question. SBU uses GRADE, an international grading system for scientific evidence. Study design is a key element in the overall judgment of each outcome measure. Other factors that can weaken or strengthen the power of the evidence are study quality, relevance, consistency, transferability, effect size, data precision, risk of publication bias, and other aspects, eg, the dose-response relationship.

Grading the strength of the evidence – four levels:

**Strong scientific evidence (⊕⊕⊕⊕).** Based on high-quality studies containing no factors that weaken the overall judgment.

**Moderately strong scientific evidence (⊕⊕⊕○).** Based on high-quality studies containing isolated factors that weaken the overall judgment.

**Limited scientific evidence (⊕⊕○○).** Based on high- or medium-quality studies containing factors that weaken the overall judgment.

**Insufficient scientific evidence (⊕○○○).** The evidence base is insufficient when scientific evidence is lacking, quality of available studies is poor, or studies of similar quality are contradictory.

The stronger the evidence, the less likely it is that the results presented will be affected by new research findings within the foreseeable future.

### **Conclusions**

*SBU's conclusions represent our overall judgment of benefits, risks, and cost-effectiveness.*

The project group included nine experts, all with extensive experience in practical diabetes care and/or diabetes research. SBU staff members contributed expertise in health economics. A medical student compiled the survey of current clinical practices. There were five external reviewers of the project.

## Evidence-graded results

### Impaired glucose tolerance (IGT)

#### Low-fat diets

- The scientific evidence is insufficient to determine whether or not low-fat diets affect the risk for onset of diabetes in people with impaired glucose tolerance and/or elevated fasting glucose (⊕○○○).

#### Low-fat diet as part of lifestyle intervention

- People with impaired glucose tolerance (or elevated fasting glucose) have a 30 percent to 60 percent lower risk of contracting diabetes within 3 years if, instead of standard practice, they receive intensive lifestyle intervention that combines a low-fat, high-fiber diet with increased physical activity (strong scientific evidence ⊕⊕⊕⊕).

#### Other diets

- The literature is lacking in randomized clinical trials and cohort studies of individuals with impaired glucose tolerance that show how the “Mediterranean diet”, low GI diet, vegetarian diet, low carbohydrate diet, or individual foods can affect their risk of developing diabetes.

#### Beverages

- The scientific evidence is insufficient to determine whether coffee consumption affects the risk of developing diabetes in people with impaired glucose tolerance (⊕○○○). The literature is lacking in studies of acceptable quality showing the effects of alcohol, milk, tea, soft drinks, and juice.

# Diabetes

## Low-fat diets

### Effects on diabetic complications and mortality

- Randomized trials have yielded insufficient evidence to determine whether low-fat diets alone can affect the risks of mortality, cardiovascular morbidity, or other complications of diabetes. Observational studies have yielded inconsistent findings regarding the effects of low intake of saturated fats, or total fat intake, on the risks of morbidity or mortality from cardiovascular disease (insufficient scientific evidence ⊕○○○).
- The scientific evidence from observational studies is insufficient to determine whether the ratio of polyunsaturated and saturated fats (P/S ratio) or cholesterol intake is associated with the risk of cardiovascular disease in people with diabetes (⊕○○○). The literature is lacking in randomized trials on the effects of unsaturated fats per se in people with diabetes.

### Effects on laboratory variables and bodyweight

- At 12 to 14 months in people with diabetes, strict, low-fat diets reduce HbA<sub>1c</sub> and bodyweight more than moderate low-fat diets do (moderately strong scientific evidence ⊕⊕⊕○). However, HDL cholesterol and triglycerides are affected similarly by strict and less-strict, low-fat diets (moderately strong scientific evidence ⊕⊕⊕○). These conclusions apply to type 2 diabetes. As regards type 1 diabetes, the scientific evidence is insufficient to draw conclusions on the association between fat intake and HbA<sub>1c</sub> (⊕○○○).

## Low-carbohydrate diets

- At 12 months in people with diabetes, moderate low-carbohydrate diets (30%–40% energy, E% from carbohydrates) and low-fat diets with high-carbohydrate content (50–60 E% from carbohydrates) have similar effects on bodyweight, HbA<sub>1c</sub>, total cholesterol, LDL cholesterol, and triglycerides (moderately strong scientific evidence ⊕⊕⊕○).
- At 12 months in people with diabetes, moderately-low-carbohydrate diets have somewhat better effects on HDL cholesterol than do low-fat diets with high-carbohydrate intake (moderately strong scientific evidence ⊕⊕⊕○).
- The effects of more extreme limitations on carbohydrate content (10–20 E%) in patients with diabetes cannot be determined due to insufficient scientific evidence (⊕○○○).
- Scientific evidence is not available to evaluate the long-term safety of moderate and extreme low-carbohydrate diets. This includes cardiovascular morbidity and other complications of diabetes.

## Other dietary factors, including the Mediterranean diet

### General

- People with recent onset of type 2 diabetes who are advised to follow a Mediterranean diet have less need for oral antidiabetic medicines and have lower HbA<sub>1c</sub>, higher HDL cholesterol, and lower triglycerides than people who are advised to follow a low-fat, high-fiber diet (limited scientific evidence ⊕⊕○○).

### Vegetables and legumes

- In people with non-insulin treated diabetes, a higher total consumption of vegetables and legumes can lower the risk of cardiovascular mortality (limited scientific evidence ⊕⊕○○). The evidence is insufficient to evaluate the effects of vegetables and legumes in people with insulin-treated diabetes (⊕○○○).

### Nuts and peanuts

- Evidence is not available upon which to determine whether consuming nuts and peanuts reduces the incidence of cardiovascular disease in diabetes. In women with type 2 diabetes, the scientific evidence is insufficient (⊕○○○). Studies on women with type 1 diabetes and studies on men are not available.

### Fish

- In women with type 2 diabetes, a higher consumption of fish can lower all-cause mortality and lower the risk for cardiovascular disease (limited scientific evidence ⊕⊕○○). We found no evidence upon which to draw conclusions concerning people with type 1 diabetes and men with type 2 diabetes.

### Unsaturated fats

- In women with type 1 diabetes, a higher consumption of n-3 fatty acids (omega-3) is associated with lower all-cause mortality (limited scientific evidence ⊕⊕○○). We found no evidence upon which to draw conclusions concerning people with type 1 diabetes and men with type 2 diabetes.

### Glycemic index (GI)

- People who have been treated with oral antidiabetic medicines for type 2 diabetes appear to achieve improved glycemic control and higher HDL cholesterol if they lower their glycemic index (GI) by around 14 units (limited scientific evidence ⊕⊕○○).

The scientific evidence is insufficient for drawing conclusions on the extent to which GI reductions below 14 units affect blood glucose levels and blood lipids (⊕○○○). We found no scientific evidence upon which to draw conclusions concerning people with type 1 diabetes.

### **Glycemic load**

- The scientific evidence is insufficient to determine whether or not people with type 2 diabetes that reduce carbohydrate content by approximately 10 E% in favor of fat (mainly monounsaturated) achieve better glycemic control than people on a diet with high carbohydrate content (50–60 E%) (⊕○○○). We found no scientific evidence upon which to draw conclusions concerning the effect of reduced glycemic load in people with type 1 diabetes.

### **Beverages**

#### **Alcohol**

- People with diabetes who regularly consume alcohol have a lower morbidity or mortality from cardiovascular disease than people who do not consume alcohol (moderately strong scientific evidence ⊕⊕⊕○) and also have lower total mortality (limited scientific evidence ⊕⊕○○).
- We found no scientific evidence upon which to draw conclusions concerning the effects of alcohol on changes in the retina or diabetic complications other than cardiovascular disease.
- The scientific evidence is insufficient to evaluate the long-term effects of alcohol on blood glucose levels and body weight in diabetes (⊕○○○).

## Coffee

- People with diabetes who consume more than two cups of coffee per day have a lower risk, than people who drink less than that amount, of dying from cardiovascular disease (moderately strong scientific evidence ⊕⊕⊕○) or other causes (limited scientific evidence ⊕⊕○○). We found no scientific studies addressing the effects of coffee on development of other complications in diabetes, or on long-term blood glucose levels.

## Other beverages

- The scientific evidence is insufficient to evaluate whether tea consumption affects the risk of cardiovascular complications or other complications in people with diabetes (⊕○○○).
- We found no scientific studies addressing the long-term effects of milk, soft drinks, and juice in people with diabetes.

## Health economics

- The scientific evidence from empirical studies is insufficient to evaluate the cost-effectiveness of low-fat diets combined with physical activity in people with diabetes (⊕○○○).
- Economic model studies suggest that lifestyle changes involving low-fat diets combined with physical activity are cost-effective in reducing the risk for diabetes.
- We found no scientific studies that analyzed the cost-effectiveness of low-carbohydrate diets in people with diabetes.



## Practice survey

A link to a Web-based questionnaire was e-mailed to contact persons in the Swedish National Diabetes Register with the request to forward the survey to a physician, a nurse, and a dietician in each unit (usually a primary care center or medical clinic). Of the units contacted, 42 percent (454 units) returned at least one survey. Of the respondents, 78 percent were nurses, 16 percent were physicians, and 6 percent were dietitians. Due to the low response rate, the results of the Web-based survey must be interpreted with caution.

Most of the respondents (65–69 percent) gave advice, in at least 9 cases out of 10, that basically complied with the European dietary recommendations for diabetes, ie, a diet that is energy adapted, low in saturated fats, high in fiber, and rich in slow carbohydrates but poor in fast carbohydrates. A common recommendation involved changing to foods generally associated with a Mediterranean diet: vegetables, beans, lentils and other legumes, nuts, oil, and fish. Advice on low carbohydrate diets was given, at least occasionally, by 25 percent of the physicians, 18 percent of the nurses, and none of the responding dietitians. This advice is more common in northern Sweden than in other parts of the country.

Many respondents (mainly physicians) reported being uncertain about whether or not the dietary recommendations concerning diabetes are evidence based. Approximately half, regardless of professional group, indicated that the patients occasionally question their dietary advice.

## Concluding Discussion and Consequence Analysis

### General comments on dietary studies in diabetes

Characteristics of diabetes include disruptions in metabolism and changes in the ability to metabolize proteins, fats, and carbohydrates. Hence, dietary advice for people with diabetes cannot outright be based on findings from studies of people without diabetes. Consequently, we did not include studies of people without diabetes or impaired glucose tolerance.

Scientific comparisons of the effects of different interventions give substantial weight to randomized clinical trials, ie, studies where the participants are randomly selected for an intervention.

Randomized studies on diets in diabetes have several obvious limitations:

- It is far from certain that people with diabetes who choose to participate in long-term dietary experiments are representative of everyone with diabetes.
- Randomized trials have often required such strict control over the entire diet of the participants that it becomes difficult to apply the results generally.
- It is difficult to conduct randomized trials that continue for many years. Consequently, it has not been possible to determine long-term effects from randomized trials, eg, complications in diabetes.

Cohort studies constitute another important source of evidence in this report. In these studies, researchers have surveyed the dietary habits of a large number of people with diabetes or impaired glucose tolerance and then followed them for several years. They have registered, for instance, diabetic complications or mortality

in study participants. Studies of this type also have certain weaknesses, the most important being that the groups compared can differ in substantially more ways than their chosen dietary habits. Researchers can statistically adjust the results for various differences, eg, smoking and physical activity. However, it is important to note that researchers have seldom adjusted for socioeconomic differences (eg, educational level), even though this is strongly associated with the risk of cardiovascular morbidity and mortality.

Including randomized clinical trials and cohort studies in the systematic literature review combines the advantages of both types of studies. Some studies provide information based on high quality while others contribute high relevance. If the results from different types of studies are consistent, interpretation is not problematic as a rule. If the results are inconsistent, quality assessment of the individual studies becomes particularly important for the overall evaluation. Study relevance is particularly a problem in dietary studies of people with diabetes, and few have been conducted in Sweden. Are studies from countries with other food cultures relevant for Swedish dietary recommendations? Some studies are limited to narrow segments of the population, eg, healthcare staff. How representative are healthcare workers in relation to the overall group with diabetes? We have chosen to include all studies in our reviews, but have evaluated each study's relevance for Swedish conditions.

Most studies included in the systematic literature review have used Food Frequency Questionnaires (FFQ) to measure food intake. The FFQ generally overreports foods considered to be healthy (eg, vegetables) while underreporting foods considered to be unhealthy (eg, those with high content of saturated fat or sugar). The total energy intake is underestimated. Consistency with other measurement methods is not necessarily good. Moreover, reproducibility is deficient, ie, the FFQ yields markedly different results in repeated measurements of the same individuals.

In several of the studies, mainly randomized trials, included in our overview the principal investigators have reported compliance with the recommended diet. Frequently, reported dropout has been high. Many of the cohort studies surveyed dietary habits on only a single occasion and later followed the participants for many years (more than 20 years in some instances) without checking whether or not they had changed their dietary habits.

Generally, these methodology problems have generated considerable “noise” in the measurements of dietary intake, substantially reducing the opportunities to detect the real associations between diet and health in people with diabetes.

## **Using diet to prevent diabetes in people with impaired glucose tolerance**

Existing studies cannot show that any particular dietary treatment actually reduces the risk of diabetes in people with impaired glucose tolerance. The primary reason for this is that too few studies have been conducted. However, there is strong scientific evidence that lifestyle intervention, combining a low-fat diet with high fiber intake and increased physical activity, prevents diabetes in people that would otherwise be at high risk for the disease. The risk is reduced by 30 percent to 60 percent over a 3-year period. In absolute figures, the number of new cases decreases from 8–11 to 3–5 per 100 person years. How much the respective components in lifestyle interventions contribute to this effect cannot be determined.

The absence of studies makes it impossible to comment on the effects of diets, other than low-fat diets, on impaired glucose tolerance (eg, Mediterranean diet, low GI diet, vegetarian diet, or low carbohydrate diet) either alone or in combination with a lifestyle program.

## **Food and beverages in people with diabetes**

### **Total fat intake**

Low total fat intake (max 30–35 E%) has been a key component in the European dietary recommendations, which are generally applied in diabetes care in Sweden. The importance of total fat intake in the development of cardiovascular disease has been questioned increasingly in recent years. If fat content is reduced, the focus shifts to the question of what other dietary components increase instead.

Our review shows that the scientific evidence is too weak to permit comments on the role of total fat intake in people with diabetes. Randomized trials are lacking, and cohort studies present conflicting results. A cautious interpretation would be that a confirmed association has not been established between total fat intake and cardiovascular disease in people with diabetes.

However, our review shows that a strict, low-fat diet has a more favourable effect on HbA<sub>1c</sub> (long-term blood glucose) and body weight than does a less-strict, low-fat diet. A combination of dietary counselling and increased physical activity provides the basis for the current recommendations in type 2 diabetes, but studies of sufficient quality are lacking when it comes to this type of combined lifestyle intervention for diabetes.

### **Saturated, monounsaturated, and polyunsaturated fats and trans fats**

Studies conducted outside the field of diabetes provide relatively consistent evidence that it is the type of fat rather than the total fat intake that influences the risk for cardiovascular disease in the population. Some of the conclusions in recently published meta-analyses are:

- High intake of trans fatty acids is associated with an elevated risk of coronary artery disease.
- Replacing saturated fats with unsaturated, especially n-3 fatty acids, reduces the risk of cardiovascular disease.
- High intake of fish is associated with lower risk of cardiovascular disease.
- Polyunsaturated fats in the diet are more clearly associated with a lower risk of cardiovascular disease than are monounsaturated fats.

Our systematic review shows that the scientific evidence for evaluating the effects of different types of fat is much less extensive when it comes to people with diabetes. The limited evidence available for n-3 fatty acids in fish concerns only women. We found no studies involving men.

### **Low-carbohydrate diets**

A particularly controversial issue in recent years concerns advice on diets with an extremely low content of carbohydrates (10–20 E%) and high content of fat, particularly saturated fat. Our literature review has shown that moderate low-carbohydrate diets (30–40 E% from carbohydrates) have roughly the same effects on laboratory variables and bodyweight as do low-fat diets with a high content

of carbohydrates (50–60 E% from carbohydrates). The exception is that moderate low-carbohydrate diets appear to yield a somewhat greater increase in the “good” HDL cholesterol (moderately strong scientific evidence). The effects of low-carbohydrate diets on the incidence of cardiovascular or other complications in diabetes have not been studied.

It must be noted that the low-carbohydrate diets investigated in scientific studies have generally involved a moderate restriction of carbohydrate content. As regards the most extreme low-carbohydrate diets, eg, Atkins or LCHF diets, we found no long-term studies that fulfilled the inclusion and quality criteria of our systematic literature review. Since these diets have received such a high level of attention in the debate, our report includes brief references to studies that did not meet the size requirements for inclusion, but have sufficient follow-up periods. The smaller studies published in this area have reported favourable effects on HbA<sub>1c</sub> and body weight compared to conventional, low-fat diets, at least in a half-year timeframe. Generally, these studies have methodological problems that make it difficult to draw conclusions.

We found no long-term studies showing the effects of low-carbohydrate diets on morbidity and mortality, and we cannot comment on the long-term safety of extreme low-carbohydrate diets. The few studies available indicate no safety problems in the short term (approximately 6 months). When experience is short and the scientific evidence for evaluating the benefits and risks of an intervention is limited, the principle of caution should be applied. It appears justified to monitor blood lipid levels and kidney function carefully in people with diabetes who choose a low-carbohydrate diet.

### **Other dietary components, eg, the Mediterranean diet**

Recognizing the limitations of scientific evidence from observational studies, the results suggest that a high intake of vegetables, legumes, and fish could lower the risk of cardiovascular morbidity and mortality in people with diabetes. Regular consumption of wine, often associated with the Mediterranean diet, is also associated with lower risk of cardiovascular disease in people with diabetes.

Current dietary advice given to people with diabetes includes a recommendation for high intake of whole grain products, which often results in a low glycemic index (GI). Our systematic review reveals limited scientific evidence for the assertion that a marked reduction in the glycemic index leads to improved HbA<sub>1c</sub> and higher HDL cholesterol, while a moderate reduction in GI appears to have insignificant effects.

### **Beverages**

Many people with diabetes seek advice on recommended types and amounts of beverages. Our systematic review shows that people with diabetes who consume alcohol regularly have a lower risk of morbidity and mortality from cardiovascular disease than do people who do not consume alcohol. Coffee drinkers have lower risk of cardiovascular disease than non coffee drinkers. Hence, we found no scientific evidence for advising people to refrain from alcohol and coffee solely on the grounds of having diabetes. Obviously, advice on alcohol must give serious consideration to pregnancy or risks for abuse.

### **Overweight, a major concern in type 2 diabetes**

Randomized clinical trials show that it is unusual for laboratory values to improve without a concurrent decline in bodyweight, regardless of type of diet. Simply participating in a study increases



one's attention to what, and how, one eats. This contributes to a reduction in energy intake and a decrease in weight.

Low-fat and moderate low-carbohydrate diets have similar effects on bodyweight in people with diabetes. In this respect, there are too few studies upon which draw conclusions concerning whether the Mediterranean diet, or similar dietary practices, differ from other diets.

### **Individualized dietary counselling**

Dietary recommendations issued by the diabetes associations in Europe and North America emphasize that diets should be individualized. Giving consideration to personal preferences is in line with the fundamental ethical principle of autonomy, which is receiving increasing emphasis in health services generally. If people with diabetes are to make independent choices, they must be well informed about the advantages and disadvantages of different diets.

People often fail to achieve the goals established during dietary counselling. Hence, complementary treatment strategies can be warranted. Our practice survey suggests that people with diabetes are often advised to shift their diet toward legumes, nuts, peanuts, and fish – or as an alternative (with some direct or indirect scientific support) moderate low-carbohydrate diets (30–40 E% from carbohydrates) and low-fat vegetarian diets. As long as the scientific evidence is so weak, any recommendations for extreme low-carbohydrate diets (10–20 E% from carbohydrates) should be considered as having insufficient scientific evidence. In people with diabetes who want to try this type of diet, consideration should be given to safety and the need for special follow-up.

### **Time to abandon current dietary recommendations?**

Individualized adaptation of diets in diabetes requires that health services give serious attention to each person's food preferences. Nevertheless, many people with diabetes still prefer to receive guidance from health services regarding their choice of diet. In other clinical situations involving the introduction of a new intervention, the new method is usually required to show substantial advantages compared to standard practice, eg, better effects, fewer side effects, or lower costs. Applying the same standards to various dietary options in diabetes, we have been unable to find evidence in this systematic review that the alternatives are superior to the usual diets currently recommended, despite the weak scientific documentation supporting current dietary recommendations.

### **Consequence analysis**

The findings from this systematic literature review do not suggest a need for major organizational changes in diabetes care in Sweden.

Impaired glucose tolerance and type 2 diabetes can be viewed as a condition on a continuous scale of disrupted glucose metabolism. The literature review reveals strong scientific evidence that lifestyle intervention in combination with a low-fat diet and increased physical activity reduces the risk of diabetes in people with impaired glucose tolerance. The effects of lifestyle intervention are so extensive and well-documented that there is strong reason to offer lifestyle intervention to this group.

In addition to glucose load, other risk factors (mainly obesity and genetic predisposition) can be used to identify people at high risk for developing diabetes. Furthermore, lifestyle interventions can be recommended in line with a model based on the programs used in the most well-executed studies. However, we found no scientific evidence by which to assess the effects that other diets, eg, low-GI diets, vegetarian diets, and low-carbohydrate diets, have on the risk for developing diabetes in people with impaired glucose tolerance.

The European dietary recommendations, which are applied in diabetes care in Sweden, emphasize the importance of individualized counselling. This places substantial demands on healthcare staff. Those responsible for dietary counselling must have the sensitivity and flexibility to assure a high degree of patient autonomy and patient influence on treatment decisions. Concurrently, those with diabetes must receive accurate information, based on scientific facts, on the advantages and disadvantages of various diets. Staff that provide diabetes care must have command of a broad repertoire of dietary options, which requires investing in basic education and continuing education for dietitians, physicians, and nurses.

Given the weak scientific evidence for dietary advice in diabetes, there is reason for caution in interpreting dietary regimens in diabetes. Numerous studies are currently under way that are probably of higher quality than many of the studies referenced in this report. The results from a few well-executed studies could possibly alter our conclusions. Consequently, we must be prepared to revisit the conclusions of this report.

## Knowledge gaps and needed research

We found major gaps in the scientific evidence for dietary recommendations in diabetes. Four deficiencies that are particularly problematic in practical dietary counselling are:

- Compliance with an intervention, regardless of type, is obviously decisive for its outcome. We found no long-term, head-to-head comparisons of the potential to adhere to different dietary recommendations in diabetes.
- Most of the studies included in this report address people with type 2 diabetes and overweight. There is an obvious lack of studies including people with type 1 diabetes (where overweight is less common than in type 2 diabetes).
- The effects studied generally address laboratory values, body-weight, or the risk of morbidity and mortality from myocardial infarction and stroke. The scientific evidence available for drawing conclusions on the importance of various diets in development of diabetes-related complications affecting the eyes, kidneys, and nerves is weak or absent. The same applies to effects on patient's experiences, eg, self-perceived health and quality of life.
- The health economic literature lacks estimates of the resource needs associated with different interventions aimed at changing the intake of food and beverages.

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# SBU Evaluates Health Care Technology

Below is a brief summary of the mission assigned to SBU by the Swedish Government:

- SBU shall assess healthcare methods by systematically and critically reviewing the underlying scientific evidence.
- SBU shall assess new methods as well as those that are already part of established clinical practice.
- SBU's assessments shall include medical, ethical, social and economic aspects, as well as a description of the potential impact of disseminating the assessed health technologies in clinical practice.
- SBU shall compile, present and disseminate its assessment results such that all parties concerned have the opportunity to take part of them.
- SBU shall conduct informational and educational efforts to promote the application of its assessments to the rational use of available resources in clinical practice, including dental care.
- SBU shall contribute to the development of international co-operation in the field of health technology assessment and serve as a national knowledge centre for the assessment of health technologies.

## **Dietary Treatment of Diabetes**

SBU's report on Dietary Treatment of Diabetes builds on a systematic, critical review of the scientific literature in the field.

The report is one in a series of reports published by SBU (Swedish Council on Health Technology Assessment).

This document presents the summary and conclusions of the full report, which has been approved by SBU's Board of Directors and Scientific Advisory Council.