NUTRITIONAL SUPPLEMENT FOR PATIENTS WITH TYPE 2 DIABETES MELLITUS FOR LIPODYSTROPHY

RELATED APPLICATION

This application is a continuation-in-part of U.S. application Ser. No. 09/634,247 filed Aug. 8, 2000, the entire teachings of which are incorporated herein by reference.

BACKGROUND OF THE INVENTION

Type 2 diabetes mellitus affects 100 to 120 million people globally and 16 million nationally, about half of whom are unaware that they have the condition. Diabetes is a metabolic disorder defined by elevated blood glucose concentrations due to insulin dysfunction. The concomitant effects of the disease are defective insulin secretions, relative (rather than absolute) insulin deficiency, insulin resistance, and abnormal blood lipid levels. The specific etiologies of the type 2 diabetes are unknown, but autoimmune destruction of β-cells does not occur as seen in type 1 diabetes. Insulin levels may be normal or elevated, but the insulin itself is defective and unable to control blood glucose concentrations. The risk of developing microvascular complications from diabetes is related to hyperglycemia, and this increases with slight increases in hemoglobin Al_c (Hgb Al_c) and with prolonged exposure to high glucose concentrations. Hyperglycemia is also implicated in causing macrovascular complications such as coronary artery disease, peripheral vascular disease, and stroke, but the relationship is less clear.

Postprandial hyperglycemia contributes substantially to overall glycemic control, and its role on the pathogenesis of the long-term microvascular and macrovascular complications of diabetes has generally been under-appreciated. Once diabetes is diagnosed, there is a progressive worsening of hyperglycemia in both the fasting and postprandial state. Since neither the oral agents (sulfonylureas) nor insulin can create the brief rise in insulin that normally accompanies a meal to mitigate this problem, the first line of therapy in type 2 diabetes is nutritional management, which as been recently referred to as "medical nutrition therapy" (MNT) (American Diabetes Association, *Diabetes Care*, 23(1):543–546 (2000)). This is integral to total diabetes management and is most effective if it involves an individualized plan devised by a registered dietitian or a nurse-dietitian team, and includes self-management training. Usually, the goals of MNT include maintenance of near-normal blood glucose levels by balancing food and blood glucose regulation medications (if prescribed), achievement of optimal serum lipid levels and blood pressure, provision of adequate calories for maintaining ideal weight, prevention and treatment of complications, and improvement in overall health.

Metabolic disorders such as hypertriglyceridemia, hypercholesterolemia and hyperglycemia are prevalent among HIV-infected individuals. Morphological changes accompany these metabolic disorders and have been referred to as lipodystrophy syndrome, although it is thought that there are two distinct syndromes. Affected individuals show fat redistribution, such as fat loss (e.g., in face) or fat accumulation (e.g., in abdominal area). These metabolic disorders may be attributed to high active antiretroviral therapy (HAART). Left untreated, the downstream adverse consequences of lipodystrophy include atherogenesis and atherosclerotic vascular disease. Thus, there is a need to provide nutritional supplementation to manage these metabolic disorders.

SUMMARY OF THE INVENTION

The invention relates to a nutritional supplement containing bioactive food-grade ingredients, which can help with the management of type 2 diabetes mellitus and metabolic disorders associated with lipodystrophy.

The nutritional supplement comprises a low glycemic index carbohydrate source, a source of protein, a source of fat, a source of sterol and/or stanol, a source of chromium, a source of salicylic acid, and a source of ginseng. In preferred embodiments, the nutritional supplement comprises, for a 45 kcal serving, from about 1 to about 25 grams carbohydrate (preferably as a combination of low glycemic index carbohydrates such as konjac, fructose, barley flakes, psyllium), from about 1 to about 10 grams protein, from about 1 to about 10 grams fat, from about 0.5 to about 4 grams plant sterol, from about 1 to about 2000 micrograms chromium (e.g., as chromium picolinate), from about 1 to about 325 milligrams salicylic acid (e.g., from a natural source like willow bark), and from about 1 mg to about 5 grams ginseng. The ranges used herein are based upon a single serving, where two servings are needed per day. Vitamins and minerals in amounts recommended daily to supplement the diet can also be optionally added.

The nutritional supplement can be made in a variety of forms, such as pharmaceutical compositions (e.g., tablet, powder, suspension, liquid, capsule, gel), nutritional beverages, puddings, confections (i.e., candy), ice cream, frozen confections and novelties, or non-baked, extruded food products such as bars. The preferred forms of the nutritional supplement are as a nutritional beverage and as a bar, such as a non-baked, extruded snack bar. In another embodiment, the ingredients of the nutritional supplement can be administered separately, such as by incorporating certain components (e.g., bitter tasting ones) into a capsule or tablet and the remaining ingredients are provided as a powder or nutritional bar. The supplement can be formulated for single or multiple daily administration, preferably twice daily, during or following the two meals in which the greatest amount of carbohydrate, cholesterol and fats are to be consumed.

The invention flier pertains to therapeutic methods for managing conditions associated with type 2 diabetes. In another embodiment, the nutritional supplement can be administered to HIV-infected individuals to prevent and/or treat metabolic disorders associated with lipodystrophy, such as insulin resistance, atherogenesis and cardivascular disease. The nutritional supplement can be administered to an individual to aid in the management of blood glucose levels and/or blood glucose levels. The risk of developing microvascular and macrovascular complications, such as atherogenesis and aterosclerotic vascular disease, associated with type 2 diabetes and lipodystrophy are lessened.

DETAILED DESCRIPTION OF THE INVENTION

The invention pertains to a nutritional supplement that provides nutritional support for people with type 2 diabetes mellitus. The invention further pertains to methods for effectively managing three aspects of type 2 diabetes [i.e., blood sugar (e.g., lowers postprandial and fasting blood glucose), blood lipids (e.g., total cholesterol fand LDL-cholesterol), and platelet aggregation] for a patient in need thereof. In another embodiment, the nutritional supplement can be administered to HIV-infected individuals to prevent and/or treat the metabolic changes associated with lipodystrophy, such as insulin resistance, atherogenesis and cardiovascular disease. Use of the nutritional supplement is not intended to take the place of the prescribed diet, exercise, and medication regimen, recommended for individuals hav-