



Virginia Weight & Wellness

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Informed Consent for the VLCD Program

Patient Name: _____

What is a VLCD (Very Low Calorie Diet)...

A very low calorie diet (VLCD) is a medically supervised diet program where patients consume 800 - 1000 calories per day. Intake of less than 1000 calories per day is not recommended without close medical supervision and monitoring.

Low calorie but balanced meal replacements (such as bars, shakes, or soups) are provided to replace all meals during the active weight loss phase (6 weeks) during which time patients have rapid weight loss. We provide the Optifast meal replacements during this 6 week low calorie phase to ensure that the very low calories (800 calories) still provide to your body the adequate amounts of protein, carbohydrate, fat, vitamins, minerals, and electrolytes.

The calorie deficit and portion-controlled diets (including liquid formulas) were developed over 25 years ago for weight reduction. They are used with patients who are overweight and who may have significant medical problems related to obesity. Such problems may include hypertension, coronary disease, diabetes, lung, joint or bone disease, and the need for non-emergency surgery. These methods of weight reduction have been utilized in hundreds of clinics in the United States. They have been described and evaluated in many professional medical journals since 1974.

Your role...

Your success will depend upon your commitment to understanding and fulfilling your obligations in a course of treatment. It is important that you be willing to:

- ◆ Provide complete answers to questions about your health, weight condition, eating activity, and lifestyle patterns so your health care professional can better understand how to help you.
- ◆ Devote the time needed to complete and comply with the course of treatment your health professional has outlined for you, including assessment, treatment, and maintenance phases.
- ◆ Allow your health care professional to share information with your personal physician.
- ◆ Keep follow-up appointments with your physician and have any blood tests or any other diagnostic measures made which may be deemed necessary during your course of treatment.
- ◆ Follow your exercise program within the guidelines given to you by your health care professional.
- ◆ It is vitally important for you to advise the clinic staff of ANY concerns, problems, complaints, symptoms, or questions even if you may think it is not terribly important, so the physician can determine if you should be seen more often. Keeping the clinic informed of any questions or symptoms you have, affords the best chance of intervening before a problem becomes serious.

Potential Benefits of Weight Loss...

Medically-significant weight loss (usually about 10 percent of initial weight, or as an example, losing 20 pounds from 200 pounds starting weight) can:

- ◆ Lower blood pressure, reducing the risks of hypertension
- ◆ Lower cholesterol, reducing the risks of heart and vascular disease
- ◆ Lower blood sugar, reducing the risks of diabetes

Other benefits may also be obtained including improved energy, reduced joint pains, improved mobility, and improved fertility amongst others. Increasing activity level can favorably affect the above conditions and has the additional benefit of helping you sustain weight loss. Weight loss and increased activity provide important psychological and social benefits, as well.

Possible side effects of Weight Loss Include...

The possibility always exists in medicine that the combination of any significant disease with methods employed for its treatment may lead to previously unobserved or unexpected ill effects, including death. Should any of these conditions occur, additional medical or surgical treatment may be necessary. In addition, it is conceivable other side effects could occur which have not been observed to date.

Lowering of Blood Pressure and Blood Sugars and other General Symptoms. When you lose weight, you may see rapid improvements in blood pressure and blood sugar. If you are on medications for blood pressure or diabetes, these may need to be adjusted over time. You may also have side effects of reduced fluid retention through increased urination, momentary dizziness, a reduced metabolism, sensitivity to cold, a slower heart rate, dry skin, fatigue, diarrhea or constipation, bad breath, muscle cramps, a change in menstrual pattern, dry and brittle hair or hair loss. These responses are temporary and resolve when calories are increased after the period of weight loss.

Reduced Potassium Levels. The calorie level you will be consuming is 800 or more calories per day and it is important that you consume the calories which have been prescribed in your diet to minimize side effects. Failure to consume all of the food and fluids and nutritional supplements or taking a diuretic medication (water pill) may cause low blood potassium levels or deficiencies in other nutrients. Low potassium levels can cause serious heart irregularities. When someone has been on a reduced calorie diet, a rapid increase in calorie intake, especially overeating or binge-eating, can be associated with bloating, fluid retention, disturbances in electrolytes, or gallbladder attacks and abdominal pain. For these reasons, following the diet carefully and following the gradual increase in calories after weight loss is essential.

Gallstones. Overweight people develop gallstones at a rate higher than normal weight individuals. The occurrence of symptomatic gallstones (pain, diagnosed stones and/or surgery) is estimated to occur in approximately 1 in 100 individuals (1%) per year who are 50 pounds or more overweight. It is possible to have gallstones and not know it. One study of individuals entering a weight loss program showed that as many as 1 in 10 had "silent" gallstones at the onset. As body weight and age increase, so do the chances of developing gallstones. These chances double for women, women using estrogen, and smokers. Losing weight--especially rapidly--may increase the chances of developing stones or sludge and/or increasing the size of existing stones within the gallbladder. Should any symptoms develop (the most common are fever, nausea and a cramping pain in the right upper abdomen or if you know or suspect that you may already have gallstones), let your physician and health care professional know immediately. Gallbladder problems may require medication or surgery to remove the gallbladder, and, less commonly, may be associated with more serious complications of inflammation of the pancreas or even death. A drug (Actigall®) is currently available which may help prevent gallstone formation during rapid weight loss. You may wish to discuss Actigall® with your weight management physician for more information.

Pancreatitis. Pancreatitis, or an infection in the bile ducts, may be caused by gallstones or the development of sludge or obstruction in the bile ducts. The symptoms of pancreatitis include pain in the left upper abdominal area, nausea, and fever. Pancreatitis may be precipitated by binge-eating or consuming a large meal after a period of dieting. Also associated with pancreatitis is long-term abuse of alcohol and the use of certain medications and increased age. Pancreatitis may require surgery and may be associated with more serious complications and death.

Pregnancy. If you become pregnant, inform your physician immediately. Your diet must be changed promptly to avoid further weight loss because a restricted diet could be damaging for a developing fetus. You must take precautions to avoid becoming pregnant during the course of weight loss.

Sudden Death. Patients with morbid obesity, particularly those with hypertension, heart disease, or diabetes, have a statistically higher chance of suffering sudden death when compared to normal weight people without such medical problems. Rare instances of sudden death have occurred while obese patients were undergoing medically supervised weight reduction, though no cause and effect relationship with the diet has been established. The possibility cannot be excluded that some undefined or unknown factor in the treatment program could increase this risk in an already medically vulnerable patient.

There is a Risk of Regaining the Weight you have lost...

Obesity is a chronic condition, and the majority of overweight individuals who lose weight have a tendency to regain all or some over time. Factors which favor maintaining weight loss include exercise, adherence to a low calorie diet, and planning a strategy for coping with weight regain before it occurs. Successful treatment may take months or even years. Medical studies of calorie deficit/portioned-controlled diets have shown varying results for percentage of patients who maintain weight loss. Additionally, if you have had fluctuations in your weight in the past, it may be more difficult to maintain the weight you lose.

Your Rights and Confidentiality...

You have a right to leave treatment at any time without penalty, although you do have a responsibility to make sure the physician knows you are discontinuing treatment and to verify your physician is able to assume medical care for you after you leave treatment.

I have reviewed this information with my health care professional or my physician, and have had an opportunity to ask questions and have them answered to my satisfaction.



Participant Name (printed)



Participant Signature

Date

I hereby certify that I have explained the nature, purpose, benefits, risks of, and alternatives to, the proposed program and have answered any questions posed by the patient. I believe the patient/relative/guardian fully understands what I have explained and answered.

Provider Name (printed)

Provider Signature

Date