

Informed Consent Form



Potential Benefits

Medically-significant weight loss (usually about 10 percent of initial weight) can:

- Lower blood pressure, reducing the risks of hypertension;
- May decrease the symptoms of arthritis and non-arthritic joint pain;
- Lower cholesterol, reducing the risks of heart and vascular disease and
- Lower blood sugar, reducing the risks of diabetes.

If you are taking medications for one or more of these conditions, dosages may need to be adjusted as your overall health improves. You agree to see our physicians as needed to have your need for these medications reassessed. Our health care professionals will share your results with your primary care physician on a regular basis to keep them informed about your progress.

Other benefits may also be obtained. 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

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 one or more of these conditions occur, additional medical or surgical treatment may be necessary. In addition, it is conceivable other side effects could occur that have not been observed to date.

Reduced Weight—When you reduce the number of calories you eat to a level lower than the number of calories your body uses in a day, you lose weight. In addition, your body makes some other adjustments in physiology. Some of these are responsible, in some participants, for rapid improvements in blood pressure and blood sugar; other adjustments may be experienced as temporary side effects or discomforts. These may include an initial loss of body fluid through increased urination, momentary dizziness, a reduced metabolic rate or 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 that have been prescribed in your diet to minimize side effects. Failure to consume all of the food, fluids and nutritional supplements or taking a diuretic medication (water pill) may cause low blood potassium levels or deficiencies in other key 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 salt and mineral balance, or gallbladder attacks and abdominal pain. For these reasons, it is essential to follow the diet carefully as well as the gradual increase in calories after weight loss.

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Gallstones—Overweight people develop gallstones at a rate higher than normal weight individuals.

The occurrence of symptomatic gallstones (pain, diagnosed stones and /or surgery) in individuals 30 percent or more over desirable body weight (50 pounds or more overweight) not undergoing current treatment for obesity is estimated to be 1 in 100 annually. For individuals who are 0-30 percent overweight, gallstones occur at about one-half that rate- or 1 in 200 annually. 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. 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/or 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 inflammation of the pancreas or even death. A drug known as Actigall, which may help prevent gallstone formation during rapid weight loss, is currently available. You may wish to discuss Actigall with your primary care or weight management physician for more information.

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

Pregnancy- If you become pregnant, report this to your health care professional and/or physician immediately. Your diet must be changed promptly to avoid further weight loss as a restricted diet could be damaging to a developing fetus. You must also stop taking any appetite suppressants, metabolic boosters or other weight loss related medications immediately. You must take precautions to avoid becoming pregnant during the course of weight loss.

Binge Eating Disorders—A binge eating disorder is defined as the habitual, uncontrolled consumption of a large amount of food in a short period of time. Participation in a calorically restricted diet has been shown, in one study, to increase binge eating episodes temporarily. Several other studies revealed reduced episodes of binge eating following a calorie deficit and portion-controlled diet. Extended binge eating episodes are associated with weight gain.

The Risk of Weight Regain—Obesity is a chronic condition and the majority of overweight individuals who lose weight have a tendency to regain some, or all, of it over time. Factors which favor maintaining a reduced body weight include regular physical activity, adherence to a restricted calorie, low fat diet and planning a strategy for coping with weight regain before it occurs.

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Successful treatment may take months or even years. Medical studies of calorie deficit/portioned-controlled diets (including modified fasting) have shown varying long term results for weight loss maintenance. In some studies, the percentage of patients who maintain weight loss has been fewer than 5% after five years. A group of patients followed for 3 years showed that patients have maintained about one half of the initial 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 during and after this program.

Please remember that being overweight or obese is a chronic condition which requires lifelong maintenance. As such, we at Thinnergy recommend that you return for periodic visits to help keep your weight management on track.

Sudden Death—Patients with morbid obesity, particularly those with serious hypertension, coronary artery disease or diabetes mellitus 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 has been established.

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 that you are discontinuing treatment and to verify that your primary care physician is able to assume medical care for you after you leave treatment.

HIPAA Patient Consent- The federal government requires all medical offices to make patients aware of their rights regarding the use of their personal health information. Our Notice of Privacy Practices is available for your review at the front desk.

By signing this form, you consent to our use and disclosure of protected health information according to the Notice of Privacy Practices available to you at our front desk. You have the right to revoke this consent at any time, in writing, signed by you. However, such a revocation shall not affect any disclosures we have already made in reliance on your prior consent. Thinnergy Medical Weight Loss provides you with this form to comply with the Health Insurance Portability and Accountability Act of 1996 (HIPAA).

You have the right to request a restriction or limitation on the medical information we use or disclose about you for treatment, payment or health care operation. This request must be made in writing. Whenever possible, we will honor your request.

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The patient understands that:

- We will not release information to any future doctor, attorney, life insurance or workman's comp company without your written consent.
- Protected health information may be used for treatment through one of your current doctors (such as your primary care physician or a specialist referral) or health care operators within our office.
- Thinnergy Medical Weight Loss has a Notice of Privacy Practices that is available for review.
- Thinnergy Medical Weight Loss reserves the right to change the Notice of Privacy Practices.
- The patient has the right to restrict the use of their information, but Thinnergy Medical Weight Loss does not have to agree to their restrictions if, for example, the request interferes with payment, daily operations or providing quality health care.
- The patient may revoke this consent in writing at any time and all future disclosures will then cease.

Resale of Products

All products purchased through this weight management program are intended to be sold through medically supervised weights management programs. By signing this Informed Consent, you agree that you will not resell any of the products purchased through this weight management program.

Appetite Suppressants—In the event that you are prescribed Appetite Suppressants and your prescription is lost or stolen; it will not be replaced without a police report. Prescription medications should not be taken by or given to anyone but the individual whose name is listed on the prescription.

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

Patient 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.

Physician Signature _____ Date _____