

Washington Center for Weight Management & Research
2800 S. Shirlington Road, Suite 505
Arlington, VA 22206
703-807-0037

Informed Consent

Our aim is to help you develop comprehensive weight management skills while you lose a meaningful amount of weight.

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 honest and complete answers to questions about your health, weight problem, eating activity and lifestyle patterns so that we can better understand how to help you.
- Devote the time needed to complete and comply with your course of treatment including assessment, treatment, and maintenance phases.
- Actively participate with the WCWMR staff in helping you manage your weight loss, including keeping food/activity records, attending group sessions and following your diet and exercise prescription.
- Allow us to share information with your personal physician, therapist or psychologist to optimize your healthcare.
- Make and keep follow-up appointments and have any blood tests taken or any other diagnostic measures made that Dr. Rubino and/or your physician may deem necessary during your course of treatment.
- Follow your exercise/activity program within the guidelines given to you by us and/or your physician.
- 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 that we and/or your physician can determine if you should be seen more often or if other evaluation is necessary. Keeping the clinic informed of any questions or symptoms you have affords the best chance of intervening before a problem becomes serious.

If you do not have a personal physician, you must agree to find one before you and Dr. Rubino begin working together.

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, type 2 diabetes, lung, joint or bone disease, sleep apnea, and reflux. 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.

FDA-approved medications for the treatment of obesity have become available. Each medication has its own associated benefits and risks. If you would like to discuss the potential addition of obesity medications for weight loss or maintenance, Dr. Rubino will review options for you and if appropriate (after assessing your medical issues, medications and individual risks) will prescribe. The effectiveness of a medication is potentiated by making the necessary lifestyle changes in food and stress management and being active. There are also individual responses to a given medication that we currently do not understand, so there may be some time finding the right “fit” for a medication that benefits you with limited to no side effects. We do not distribute medication. All medication prescribed is evidence-based. Your insurance company may or may not choose to pay for the medication. We will assist by submitting prior authorization forms.

Potential benefits

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

- 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, improving diabetic control.

If you are taking medications for one or more of the conditions, dosages may need to be adjusted as your overall health improves. Dr. Rubino may suggest adjustments or recommend that you see your personal physician to have your need for these medications reassessed. We will share your results with your physician on a regular basis so the physician is informed about your progress. You agree to follow these recommendations regarding medication adjustment as well as evaluation of any health care situations that may arise.

Increasing activity level can favorably affect the above conditions and may have the additional benefit of helping you sustain weight loss. Weight loss and increased activity may 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 ill effects occur, additional medical or surgical treatment may be necessary. In addition, it is conceivable that other side effects could occur, which have not yet been diagnosed or observed.

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. As a result of this weight loss, your body makes some other adjustments in body processes. Some of these adjustments are responsible, in some participants, for improvements in blood pressure and blood sugar and your medications may need to be adjusted. However, you also may experience other temporary side effects or discomforts, including an initial loss of body fluid through increased urination, momentary dizziness, a reduced metabolic rate or metabolism (the rate at which you convert food to energy), 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. Generally, these responses are temporary and resolve when calories are increased after the period of weight loss. Please discuss these with Dr. Rubino if they occur. 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, following the diet carefully and following the gradual increase in calories after weight loss, as prescribed by us, WCWMR and/or your personal physician, is essential.

Reduced Potassium Levels. The calorie level you will be consuming is 1000 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 and 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. We monitor potassium throughout participation in the program. Please inform Dr. Rubino or staff member if your physician prescribes a diuretic.

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, and for individuals who are 20-30 percent overweight, and 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 at

the onset. As body weight and age increase, so do the chances of developing gallstones. These chances double for women, women using estrogen, who smoke, and for men and women with type 2 diabetes. Losing weight—especially rapidly—may increase the chances of developing stones or sludge and/or increasing the size of existing stones within the gallbladder. The most common symptoms of gallstones are fever, nausea and a cramping pain in the right upper abdomen. If you develop any of these symptoms or if you know or suspect that you may already have gallstones, let your physician and Dr. Rubino and the WCWMR staff 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. Drugs are available that may help prevent gallstone formation during rapid weight loss. You may wish to discuss these drugs with Dr. Rubino or your personal physician.

Pancreatitis. Pancreatitis, or an infection in the bile ducts, may be associated with the presence of gallstones and the development of sludge or obstruction in the bile ducts. The symptoms of pancreatitis include pain in the upper mid-abdominal area or back pain, 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, use of certain medications, having type 2 diabetes and increased age. Pancreatitis may require hospitalization and may be associated with more serious complications and death.

Pregnancy. If you become pregnant, report this to us/WCWMR staff and 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.

Eating Disorders. Binge eating disorder is defined as the habitual, uncontrolled consumption of a large amount of food in a short period of time. The effect of dieting on binge eating is unknown and studies have conflicting results. Participation in a calorically restricted diet has been shown in one study to increase binge eating episodes temporarily. Several other studies have demonstrated reduced episodes of binge eating following a calorie deficit and portion-controlled diet. Please notify WCWMR if you are bingeing. Bulimia (vomiting) increases the risks for low potassium and other problems. You agree to notify the staff of any bulimic behavior and your program may need to be changed.

The risk of weight regain...

Obesity is a chronic condition, and the majority of overweight individuals who lose weight may regain all or some of it over time. Despite the improvement in health conditions like diabetes, sleep apnea, chronic pain, etc., the normal physiologic reaction of the body is to

send hormonal signals that increase appetite, hunger, cravings in an effort to regain the weight. These signals plus our environment increase the risk for this regain. Factors that help to maintain a reduced body weight include regular physical activity, keeping records supporting mindful adherence to a food plan, eating breakfast daily, weighing in weekly, implementing strategies for stress management and developing a plan for weight regain if it occurs. Several medications have been approved for the treatment of obesity. Use of these may be helpful in the maintenance stage to help counter the body's response and efforts to "protect the body's energy stores" and regain the weight. Successful treatment may take months or even years. Medical studies of calorie deficit/portioned-controlled diets (including modified fasting) have shown varying results for patients who maintain weight loss. Some studies have shown that fewer than 5% of weight loss patients were able to maintain a reduced body weight after five years. Another study showed that after three years, weight loss patients, on average, maintained about one half of their initial weight loss. Most recently, the Look Ahead trial (an intensive lifestyle intervention study) showed that nearly 40% of participants who lost >10% of initial weight at year 1 maintained this loss at year 8.

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 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.

Your rights and confidentiality

You have a right to leave treatment at any time although you do have a responsibility to make sure your personal physician knows you are discontinuing treatment and to verify your physician is able to assume medical care for you after you leave treatment.

Your signature below represents your permission, understanding and commitment to the above.

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 understands what I have explained and answered.

_____ Date _____
Domenica M. Rubino, MD

I, the undersigned, have reviewed this information with Domenica Rubino, MD and have had an opportunity to ask questions and have them answered to my satisfaction.

_____ Date _____
Participant Signature

I have received a copy of this signed consent form _____
I don't wish to receive a copy. _____

_____ Date _____
Participant's Initials