



## **PATIENT INFORMED CONSENT FIRST STEP / BETTER WEIGHS**

**The Metabolic Nutrition Program recommends that you consult your personal physician before starting this or any weight loss program.**

1. The Metabolic Nutrition Program is a medically-supervised program designed for the treatment of individuals who are over desirable weight, and who may have significant medical problems related to obesity. Such problems include but are not limited to high blood pressure, coronary heart disease, diabetes, gallbladder disease, lung disease, joint or bone disease, and the increased risk associated with surgery. The program has been thoroughly tested and used in centers throughout this country. The results of its use have been reported in professional medical journals.

**The Metabolic Nutrition Program includes:**

- a. A period of very-low calorie diet, during which the patient has either a full liquid diet consisting of 650 liquid calories per day (First Step), or a modified fast which includes 400 liquid calories and 450 food calories per day (Better Weighs). The patient is seen regularly by a program physician and has 60 minute weekly group sessions with a program counselor. Laboratory tests are drawn biweekly for full fast diet and monthly for modified fast.
- b. Four weeks of reintroduction to food during which the patient gradually interchanges the liquid supplement for solid food. Weekly group therapy and medical visits continue and intensive nutritional education, dietary planning, and life-style changes begin.
- c. Obesity is a chronic illness, and as such, a one to two year commitment to the maintenance program is strongly recommended. Agreements are signed for six month intervals which include monthly physician visits and weekly sixty minute therapy and dietary groups.

2. **Activity during the weight loss period:** During the very-low calorie diet, all usual activities of work are permitted. During weight loss, individuals may become momentarily dizzy; therefore activities which might accentuate dizziness or cause danger if one became momentarily dizzy should be avoided. These activities include hot steaming baths, whirlpool baths, scuba diving, swimming alone, diving off boards, piloting a plane, horseback riding, motorcycle riding, hang gliding, etc.

3. **Potential side effects:** Rapid weight loss (losing weight greater than 1-1/2 to 2 pounds per week) may cause serious health problems. Since rapid weight loss may occur during treatment in the Metabolic Nutrition Program, the program requires that you see a program physician regularly during the course of treatment.

Temporary side effects which may occur include sensitivity to cold, dry skin, rash, dizziness, fatigue, diarrhea or constipation, muscle cramps, bad breath, change in menstrual patterns, and hair loss that regrows after the period of dieting.

The clinical appearance of previously undiagnosed gallstones, with or without acute inflammation of the gallbladder, is a potential side effect of dieting. It is suspected that deviation from the recommended protocol, particularly ingestion of rich foods, may increase the incidence of gallbladder related complications. Gallstone problems may require surgical removal of gallbladder. Medication may be

prescribed in an attempt to prevent the formation of gallstones. Additional information related to this issue is available from program physicians.

**4. Unexpected ill effects, including sudden death:** There is a possibility, as always in medicine, that the presence of any disease, whether previously diagnosed or not, in combination with methods employed for its treatment, may lead to unexpected ill effects, including death. Obese individuals, particularly those with serious hypertension (high blood pressure), coronary artery disease (poor circulation to the heart) and diabetes (sugar diabetes) have a statistical higher risk of suffering sudden death than normal-weighted people without such medical problems. Instances of sudden death have occurred while obese subjects were undergoing weight reduction by very-low calorie diets, but the reported incidence in this program has not exceeded the reported background incidence in similarly obese people. The possibility cannot be excluded that some undefined or unknown factor in the treatment program could increase this risk in a medically vulnerable individual.

**5. Risks of gaining weight:** For many dieters weight loss is only temporary. Only permanent life-style changes, such as making healthful choices and increasing physical activity, promote long term weight loss, according to medical experts. In the Metabolic Nutrition Program, individuals who participate actively in the maintenance program are more likely to maintain their weight loss as compared to those who do not complete treatment. The benefits of achieving a reduced body weight are significant, (improved mobility and exercise in tolerance, improved blood pressure, improvement in diabetes, improved blood cholesterol levels, reduced risk of gallstone formation, etc.); however, these benefits will be diminished if weight loss is not sustained.

Qualifications of this program's staff are available on request.

## **PATIENT ACKNOWLEDGEMENT**

6. I hereby authorize and direct the Metabolic Nutrition Program at 2516 Samaritan Drive, Suite B, San Jose, California 95124, and such assistants as may be selected by them, to administer care and treat me, and I consent to be treated with the very-low calorie diet described in this document.

7. I understand that the purpose of my participation in the program is to be treated for obesity and its associated medical complications; I further understand that it is my responsibility to obtain a primary care physician, should I not have one, at the time or before I begin treatment in the program.

8. I understand that my responsibilities and obligations as a participant in this program are as follows:

a. I will make participation in the program and changing my life-style long-term a priority.

b. I will be prompt in my clinic attendance each week. I understand each clinic visit is approximately 1 to 1 1/2 hours long, including the medical visit and group session. I will allow extra time on the weeks I have extra tests or meetings scheduled.

c. I will attend group sessions each week. These sessions will assist me in improving my eating and exercise habits. I understand that my attendance in the group session is essential to my success.

d. I agree to follow to the best of my ability the dietary and program protocols as explained to me by the clinical professional staff.

e. I will notify the program physicians regarding any changes in my medications or other changes in my medical status or of any contemplated surgery or other medical procedures.

f. I will adhere to the medical portion of this program. This includes seeing the program physician and having blood test done routinely and having an electrocardiogram performed periodically, as well as having any other tests my physician determines may be necessary.

g. I will allow lab results, EKG results or other medical information to be sent to the private physician whom I designate to receive it.

h. I will participate in an organized maintenance program for at least 12 months following the weight loss program. I understand that failure to participate in maintenance treatment may result in rapid regain of the weight I lose in this program.

9. I have been given the following financial information:

a. I understand the program staff will provide me with all necessary documentation to complete my financial records. I may contact the program staff anytime I have a question or problem in this area.

b. If I choose to discontinue the program at any time, I understand that any monies paid are not refundable.

c. I agree to pay for each four weeks of the program in advance. The fees include MNP First Step supplement (except in the maintenance program), regularly scheduled medical visits, medical tests and group sessions. Any other medical visits or medical tests or individual consultations with professional staff incurred throughout treatment will be billed additionally.

d. I understand that, in general, maintenance and nutritional supplements are not reimbursed by insurance companies, including Medicare. The program does not guarantee insurance reimbursement. For questions about my own situation, I understand that I need to consult my own insurance plan directly.

10. I am advised that no guarantee can be made concerning the expected results of the product and the program described above.

11. I hereby acknowledge that the above described information has been disclosed to me, that I have had an opportunity to ask questions, and all questions which I asked about the treatment described have been answered in a satisfactory manner.

12. I understand that this consent extends to the original period of participation in the program.

13. I have read and understood this informed consent. All blanks were filled in prior to my signature.

14. If I deviate from the recommended procedures, I may increase the risk of potential side effects or ill effects mentioned above.

---

Patient signature

---

Date