

Informed Consent

Treatment Plan:

In choosing to ask Ed J. Hendricks, M.D. to assist me with weight management, I understand that the treatment plan prescribed may include any or all of the following:

1. A calorie restricted diet which will have ratios of basic nutrients different from the FDA approved pyramid diet. Specifically the diet will incorporate protein in amounts higher than the daily allowances and carbohydrates lower than the daily allowances recommended by the FDA. I understand that I will have to continue calorie restriction to some degree after I lose weight in order to maintain the weight loss.
2. An exercise plan.
3. Assistance with modification of my current behaviors which may have induced weight gain with respect to eating, food selection, and physical activity.
4. Non-prescription vitamins, minerals, herbals, and food supplements to assist with weight loss which have not been approved or deemed necessary by the FDA, other government agencies, or medical authorities for such use.
5. Non-prescription vitamins, minerals, herbals, and food supplements to assist with health maintenance which have not been approved or deemed necessary by the FDA, other government agencies, or medical authorities for such use.
6. Prescription drugs and pharmaceutical agents which have been approved by the FDA for weight management. I understand that the FDA, taking a cautious stance has recommended certain restrictions on the use of these drugs. I understand that Dr. Hendricks is experienced in the use of these drugs and that he may prescribe them in higher doses and for longer periods than the FDA recommends.
7. Prescription drugs and pharmaceutical agents which have proven safe and useful in weight management but which have not been approved by the FDA for such use.

I understand that Dr. Hendricks will not recommend any treatment modality unless he believes the evidence that such treatment is both effective and safe. I understand that there are numerous controversies surrounding medical weight management treatment methods and that some physicians, including my own physician(s) will disagree with Dr. Hendricks' treatment methods. I understand that I have the right to reject any element of the treatment plan at any time if that is my choice without fear that Dr. Hendricks will terminate our relationship because of such rejection. I understand that if I reject any treatment element that Dr. Hendricks will continue to assist me with my weight management to the best of his ability.

I understand that if another physician recommends discontinuing any treatment recommended by Dr. Hendricks that it is my responsibility to thoroughly discuss this controversy with Dr. Hendricks or another practitioner in Dr. Hendricks' office so that I can make an informed decision whether to continue or discontinue the treatment in question and so my patient record at Dr. Hendricks' office accurately reflects my treatment plan.

Risks versus Benefits and Risk Management:

Everything in life is associated with some level of risk. Action always has associated risk; inaction always has inherent risk as well. The trick in achieving and maintaining health is selecting which health risks to avoid. In other words – deciding to consciously identify and manage one's risks. This medical practice is a patient centered medical practice because we believe that a combination of a well informed patient and a well trained, broadly experienced, up-to-date medical practitioner can be highly successful in managing that patient's health risks. Government-centered or insurance-centered medicine, or managed-care, where bureaucratic rules are imposed rather than informed individual choices cannot even come close to achieving the same level of success.

Risks Associated with Overweight or Obesity:

I understand there are numerous health risks associated with being overweight which include but are not limited to:

1. Premature death
2. Cardiovascular disease such as coronary atherosclerosis, hypertension, and heart attack
3. Diabetes
4. Metabolic syndrome
5. High cholesterol and dyslipidemia
6. Gall bladder disease
7. Sleep apnea
8. Asthma
9. Arthritis
10. Fatty liver, cirrhosis, and liver cancer
11. Cancer of the uterus and breast in women and prostate in men
12. Depression

I understand that even small increases in weight, if due to excess fat accumulation in the abdomen, is associated with these risks and that the greater the increase in fat tissue, the greater the increase in risk. I understand that excess fat can aggravate and make worse any other chronic illness, making medical management of such illnesses more difficult.

General Risks Associated with Proposed Treatment:

I understand that there are certain risks associated with any treatment which include but are not limited to the following:

1. Calorie restriction can lead to essential vitamin and mineral deficiencies. I understand this risk is small and can be prevented with supplements. Some experts believe that eating more protein than the RDA is harmful to the kidneys. Patients with chronic kidney disease may have to eat less protein than we advise but there is no credible evidence that higher protein intake is harmful to normal kidneys.
2. An increase in physical activity and exercise can result in injury. Some overweight patients develop fractures in their feet if they begin an ambitious walking program. I understand Dr. Hendricks will recommend gradual increase in exercise to minimize this risk. Some patients who have occult heart disease have heart attacks or develop tachycardia or an arrhythmia when beginning exercise. I understand Dr. Hendricks will insist on an EKG to diminish but not eliminate these risks.
3. I understand that the risk of failure with attempts at behavior modification is high.

4. The addition of vitamins, supplements and minerals carries a risk of allergic reactions, and other adverse effects. There is a risk that these will not have the desired beneficial effect.
5. The addition of prescription drugs carries a risk of allergic reactions, and other adverse effects which are discussed more thoroughly below. There is also a risk that these will not have the desired beneficial effect.
6. There is a risk that the proposed treatment plan will prove ineffectual in producing weight loss. I understand that patients who do not lose as much weight as desired have increased risk of developing depression.

Rarely Encountered Specific Risks of Weight Loss/Maintenance Drugs:

Some of the weight loss drugs used in the past proved to have unexpected harmful effects. The fenfluramine in the “Phen/Fen” combination is an example. Although the harmful drugs are no longer in use, as a result of past bad experiences, the FDA and some physicians have concluded that all weight management drugs are ineffective and highly likely to be bad. The truth is that these drugs are both effective and safe when used properly for weight management. You should be aware of the worst of the FDA’s fears for phentermine and for diethylpropion which include but are not limited to the following:

1. Pulmonary hypertension or high blood pressure in the arteries in the lung is a rare but fatal disease. The incidence is about one per one million persons per year. Fenfluramine and some other older but no longer used weight management drugs may have rarely triggered pulmonary hypertension in some patients. Phentermine and the other weight management drugs we use today have not produced pulmonary hypertension. Your risk for developing pulmonary hypertension is the same whether you take a weight management drug or not.
2. Heart valve disease occurred in some patients who took fenfluramine. Heart valve abnormalities have not been described in patients who have taken phentermine alone. There is a high incidence of heart valve abnormalities in the general population. Your risk for developing a heart valve abnormality goes up with advancing age. Your risk for developing a heart valve abnormality is the same whether you take a weight management drug or not.
3. Hypertension – although the FDA warns of the possibility of phentermine causing hypertension, the truth is being overweight increases your blood pressure and lowering your weight lowers your blood pressure – phentermine will help lower your blood pressure if it helps lower your weight. Your risk of a lasting increase in blood pressure abnormality is the same whether you take a weight management drug or not.
4. Addiction to phentermine has never been reported in the peer-reviewed medical literature – your risk of becoming addicted to phentermine is much less than one in a million.
5. Serotonin syndrome is an extraordinarily rare condition in which a patient taking an SSRI antidepressant becomes seriously ill due to too much serotonin. This occurs only in patients taking high doses of Prozac or a like medicine and has never been observed due to the weight management drugs we use today.
6. A very few cases of psychosis attributed to weight management drugs have been described. Your risk of developing a psychosis from a weight management is extremely low. Your risk for developing a psychosis is the same (i.e. about 1 in 10,000 according to a WHO 10 nation study) whether you take a weight management drug or not.

More Commonly Encountered Specific Risks of Weight Loss/Maintenance Drugs:

Occasionally patients experience less serious side effects due to weight management medications. In general these are mild, occur soon after starting the drug, and fade or vanish promptly if the drug is continued or discontinued. If you have any adverse reaction it’s best to stop the drug until you have discussed it with Dr. Hendricks or one of the practitioners. The following are stimulant side effects and may be seen with phentermine, diethylpropion (Dipro), and phendimetrazine:

1. Stimulation – an occasional patient will find the stimulant effect excessive but for most patients the stimulant effect is about the same as a strong cup of coffee. Many patients say they have more energy on these drugs. If you feel over-stimulated and discontinue the drug, the effects wear off in a few hours. Patients who take these drugs for months and then stop abruptly may find they have low energy for a few days but their energy soon recovers to normal levels.
2. Insomnia – perhaps one in ten patients report sleeping less when they start one of these drugs. For most, this effect fades with time. If insomnia persists, other medications can be added to counter this effect. Insomnia, if it is drug induced, disappears if the drug is discontinued.
3. The drugs are weak anticholinergic agents and in some patients can cause dry mouth, change in sweating pattern, decrease gastrointestinal motility, contraction of the bladder outlet sphincter, and a variety of other symptoms. These may fade if the drug is continued, but may not until the drug is discontinued.
4. These drugs can produce or aggravate pre-existing jaw clenching and can aggravate TMJ.
5. Other side effects are possible. You should ask us if you have any untoward reaction on your program.

I have read this informed consent and understand the risks involved in doing nothing, remaining at my current weight or gaining weight, versus undertaking to lose weight. By signing below I accept these treatment risks.

Dr. Hendricks and Clinical Observation Research:

I understand that Dr. Hendricks constantly reviews his patients’ records and occasionally submits scientific papers for presentation at medical meetings or for publication in the peer-reviewed medical literature. I understand that observations from my medical record may be published anonymously but that my identity will not be revealed, nor will any information be published which potentially could reveal my identity. **Dr. Hendricks has my permission to publish anonymous observations from my medical record at any time without the need for my specific permission for specific observations or for specific reports.**

Patient Name Printed: _____

Patient Signature: _____

Date: _____ Witnessed: _____