medical guidelines

BOOKLET

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Program Overview-Full Plan

VLCD's are intended for use as part of the management of Type I and Type II obesity (BMI between 30 and 40) where there is an increased risk of a number of weight-related comorbidities, including:

- Type II diabetes
- Hypertension
- Hyperlipidemia
- Certain types of cancers

This protocol can be beneficial in reducing the risks during surgery in obese patients.

Additionally, the program can be used for individuals with a BMI between 27 and 30 if they currently have obesity related co-morbidities.

For those who are at medical risk due to overweight and obesity, we have found our multidisciplinary approach to be most successful in helping patients lose the initial weight and sustain a healthy weight for life. Losing the weight is a critical first step, but it is only with our self-monitoring, skill building and educational components that the necessary modification in lifestyle can be achieved. The technology tools provided with the Program act as a guide for delivering the program and are designed to augment the care provided by the physician, making more efficient use of patient/provider interaction.

This protocol has been developed based on the extensive research and clinical experience of leaders in the field of obesity medicine. It is our belief that this type of protocol is best delivered by health professionals in order to provide appropriate guidance, monitoring and continuity of care.

Identifying Patient Fit

Who is a fit for the Program?

The Program is designed for people who would benefit from weight loss. If your patient has a BMI of 30 to 40 or 27 and greater with obesity related co-morbidities such as type II diabetes, hypercholesterolemia and hypertension, they may be a good candidate for the Program. In general if your patient needs to lose at least 30-40 lbs, they may be well suited for this program.

Who is not a fit for the Program?

Individuals, who are pregnant, have active substance abuse or active disordered eating such as anorexia nervosa or bulimia should not participate in the Program. Additionally, anyone with a milk protein allergy (not to be confused with lactose intolerance) should not be placed on the Program.

Precautions

Aside from the absolute contraindications to the Program, there are certain patient populations who need special consideration when evaluating whether it is the appropriate time to start an aggressive diet regimen.

Very Low Calorie Diet (VLCD) Background & History

While the VLCD diet originated in the 1920s as a way to achieve more rapid weight loss, the diet has gone through various iterations through the years as science evolved both better data and protein sources. VLCDs came under scrutiny in the 1970s after inadequate medical supervision and insufficient protein and nutrition led to patient health challenges.

However, with continued years of research and the development, the VLCD protocol is now widely used, and is best delivered under physician supervision.

The VLCD diet has gone through various iterations through the years as a result of continued research, updated medical knowledge and better quality liquid protein sources. In the 1920's, the VLCD was originally created as a way to achieve larger and more rapid weight loss than provided by conventional diets. Widespread interest in the VLCD began in the 1970's with the introduction of the "protein-sparing

> “Due to advances in research and product development, a VLCD is once again considered an acceptable treatment for individuals who are medically supervised.”

modified fast”, consisting of 650-800 daily kcal provided by high-protein foods (lean meats). The protein was rich in essential amino acids (high biologic value) in order to maintain nitrogen balance. This food-based diet was then adapted and refined by the late 1970’s into a liquid-based protocol to improve both results and compliance. It was during this time that the, VLCD’s came under scrutiny and fell out of favor due to reported cases of sudden death -- a result of inadequate medical supervision and insufficient protein and nutrition.

Due to advances in research and product development, a VLCD is once again considered an acceptable treatment for individuals who are medically supervised and for whom a loss of significant weight at a more rapid pace than brought about by conventional diets is deemed beneficial. More conservative use and improvements in the quality and balance of liquid-based protein sources (ones that had higher biologic value, usually from dairy and egg sources) as well as the addition of carbohydrates, healthy fats, vitamins and essential minerals, have contributed to the safer practice of VLCD diet protocols.

VLCD that provides 800 kcals/day and allows for the proper ingestion of essential macronutrients, vitamins, and minerals while avoiding the loss of lean body mass. By providing 800 kcals/day, patients tend to comply better with the protocol while also avoiding the dangers of starvation and other severe side effects associated with fasting.

Fresh Steps Full Plan

TOTAL CALORIE TARGET/DAY: 800KCAL

Here is an example of the macronutrient breakdown for patients following the Fresh Steps Full Plan:

- Eating Event 1: Smoothie Meal Starter + Chocolate Indulgence FP - 160 calories
- Eating Event 2: Smoothie Meal Starter + Vanilla Bean FP - 160 calories
- Eating Event 3: Pasta Meal Starter + Asian Inspired FP - 160 calories
- Eating Event 4: Hot Meal Starter + Mushroom FP - 160 calories
- VLC Snack Bar/Chip: VLC Zesty Lemon Bar - 160 calories

Total Calories: *800 calories*

PROTEIN: 46%
CARBS: 24% (50g total carbs - 23g fiber = 27g net carbs)
FAT: 30%

Fresh Steps Partial Plan

TOTAL CALORIE TARGET/DAY: 1,000KCAL

Here is an example of the macronutrient breakdown for patients following the Fresh Steps Partial Plan:

- Breakfast: Black Bean Scramble (200 calories) – Egg meal starter used
- Lunch: Peanut Butter & Jelly Smoothie (208 calories) – Smoothie meal starter used
- Dinner: Grilled Chicken Kabobs (441 calories) – Full grocery meal
- Snack: VLC Salty Toffee Pretzel Bar (160 calories)

Total Calories: *1,009 calories*

PROTEIN: 100g x 4g/kcal = 400kcal/1,009kcal = 38%
CARBS: 59g x 4g/kcal = 236kcal/1,009kcal = 22%
FAT: 46g x 9g/kcal = 414kcal/1,009 = 40%

Section 1: Program

Overview

The Program has been designed to address the key areas of weight loss in order so patients can achieve long-term results and overall improved health outcomes. We accomplish this through a balanced approach that includes not only carefully calibrated foods, but a combination of support, both in-office with a health care provider and through the use of online and smart phone tools. Additionally, our diet protocols have been carefully developed to transition a patient from rapid weight loss to a less aggressive weight loss plan and eventually to a maintenance plan for long-term weight management and healthy living.

Support

Office Visits

MONTH 1

During the first month of the program, the patient is required to make one office visit per week. The first visit of the program is the most involved and for the purpose of conducting a thorough history and physical exam which will provide medical clearance for the patient to participate in the program. The following three, weekly office visits are brief and for the purpose of conducting a weigh-in, providing medical supervision and promoting accountability to the program.

Initial Visit

In addition to providing medical clearance to start the Phase 1: VLCD protocol, this appointment is also used to uncover any concerns or questions that the patient may have about the program. Reinforcement of program commitments and identification of any potential conflicts to success (such as holidays, travel, unsupportive family/friends) should be discussed.

It is at this time that the patient reads and signs the Patient Informed Consent.

Areas Covered:

1. Health assessment
2. Setting expectations
3. Weight check
4. Setting a weight loss goal
5. Reviewing the dashboard
6. Reinforcing delivery of educational topic

1. Health Assessment

The initial assessment is the first step in beginning the program. This assessment includes several components:

a. Medical history *

b. Screening & baseline laboratory tests

c. EKG for high risk individuals

a) Medical history - baseline data collection:

1. Weight
2. Height
3. BMI using chart provided in Section 3 or use auto calculate function in the initial assessment Progress Note
4. Blood Pressure
5. Pulse
6. Waist Circumference measured at the level of the iliac crest on an axis parallel to the floor. Waist circumference is an important measurement to determine overall health risk. A woman who has a waist circumference greater than 35" and a man with a waist circumference greater than 40" has a greater overall risk for disease no matter the BMI

**If practice has standard history forms, it is possible to have patients fill these out prior to the visit to make more efficient use of appointment time. Information should include: weight history, family medical history, review of systems, review of allergies, history of substance abuse, review of current medications and other baseline data.*

b) Screening & baseline laboratory tests - required baseline fasting labs:

1. Metabolic Panel: glucose, ALT/AST, Alkaline phosphatase, Bilirubin, BUN , Creatinine, Calcium, Potassium, Sodium, Chloride, Magnesium, Albumin, Total Protein, Uric Acid, CK
2. Lipid Profile: Total Cholesterol, Triglyceridd, HDL, LDL
3. TSH
4. CBC and Platelets

c) EKG for high risk individuals – baseline 12 lead electrocardiogram

For additional monitoring guidelines, please refer to ***Section 3: Medical Training &Supervision.***

2. Setting Expectations

Ideally, the discussion about the weight loss and likely outcomes should take place before the patient is registered in the program. Many patients will have higher than realistic expectations for how much weight they can lose and it is the provider's role to negotiate an achievable goal with the patient.

The rationale for the Program is to produce a significant weight loss in a relatively short period of time so the patient can see rapid improvement in the co-morbidities associated with extra body weight and they become vested in the process of making the necessary behavior and lifestyle changes necessary to keep the weight off.

The Program is best suited for individuals wishing to lose 30-50 pounds. While there are many cases of individuals who have lost more weight than this on a VLCD program, these tend to be the exception rather than the rule. The rate of weight loss is generally in the range of 2-5 pounds per week depending on the individuals starting weight.

- Men and individuals with a BMI> 35 tend to lose weight faster (3-5 pounds per week).
- Women and individuals with a BMI of 30-35 typically lose 2-3 pounds per week.

It is important to emphasize to the patient that long-term success involves a commitment to the transition and maintenance phases of the diet. Often, adhering to the weight loss protocol proves to be the easy part while learning and applying the skills and knowledge obtained during the transition and maintenance phases of the diet takes more effort to cement into lifelong healthy behaviors. Individual results vary according to compliance and other factors like exercise levels.

3. Weight Check

Before setting your weight loss goal, you will need to take the patients starting weight. The “weigh-in” is at the core of any weight management program, but how this simple activity is handled will reflect the culture of your program. These simple guidelines will ensure that what is an extremely sensitive area for most patients is handled professionally and will promote a patient-centered culture in your program and practice.

Weigh-in Guidelines:

a) Ensure that you have a professional scale that will accommodate the heaviest patients you intend to weigh. There are few things more humiliating for a patient than to step on a scale only to realize that they have surpassed the maximum limit. The Program is best suited for individuals with 30-50 pounds of excess weight and so most professional grade scales will easily handle this requirement.

b) Ensure the scale is located in a private location. Again, this is a very sensitive area for most patients and creates a high degree of vulnerability and as such the weigh-in must be performed in a private setting.

c) Avoid making any comments about the patient’s weight at the weigh-in. It is easy to make a positive comment or give praise if the patient has experienced weight loss but in the event of weight gain there is the implied message that they havefailed. The most effective strategy at the weigh-in is to simply ask the patient how they feel about their weight.

4. Setting a Weight Loss Goal

In order to set a weight loss goal, one has to determine an "ideal body weight" for the patient. While the Body Mass Index (BMI) has some limitations (overestimates fatness in muscular individuals, based on Caucasian individuals etc.), it is the most useful and practical tool to determine goal weights for patients. Data from the Framingham Heart Study, the Nurse's Health Study and others suggest that a BMI of approximately 22 kg/m^2 for women and $23kg/m^2$ for men is associated with minimizing disease risk.

Once a total weight loss goal is established with the patient, the VLCD phase is designed to produce the first 80% of the weight loss. For example, if the total weight loss goal is 30 pounds, the VLCD phase is prescribed until the patient loses 24 pounds before being placed on the Phase 2: Transition diet protocol described above in order to lose the remaining 8 pounds. It is critical that the patient progress to the maintenance phase of the program after reaching the weight loss goal in order to solidify the behaviors required to maintain this weight loss.takes more effort to cement into lifelong healthy behaviors. Individual results vary according to compliance and other factors like exercise levels.

Phase 1	Phase 2	Phase 3
80% of Total Weight Loss Goal	Remaining 20% of Weight Loss Goal	Maintain Weight Loss Goal

For patients with high BMIs, setting short-term goals may be less intimidating and provide motivation to continue with the diet. For instance, a 5-10% weight loss has been associated with a significant decrease in health risks. For a 5'6" woman weighing 190lbs, setting the first goal in Phase 1 at a 5% loss (or 9.5 lbs) seems much more attainable than focusing on the total of 50lbs that she needs to ultimately lose in order to reach a BMI of 22 or a weight of approximately 140lbs.

Example Patient: Nicole Smith		
Initial Stats		
Height: 5'7"	Weight: 198 lbs	BMI: 31 (obesity class I)
Goals		
Ideal Weight: 140 lbs	Ideal BMI: 22	Total Weight Loss Goal: 58 lbs
Phase 1 Weight Loss Goal (805 of Total Goal): 46.4 lbs		
Phase 1 Incremental Weight Loss Goals (80% of Total Goal)		
Goal #1: 9.9lbs (5%)	Goal #2: 19.8lbs (10%)	Goal #3: 46.4lbs (65%)
Current Weight 188.1 lbs	Current Weight 178.2 lbs	Current Weight 151.6 lbs
Start Phase 2: Transition after 80% Total Weight Loss		
Phase 2 Starting Weight: 151.6 lbs	Phase 2 Weight Loss Goal: 11.6 lbs	Phase 2 Ending Weight: 140 lbs
Enter Phase 3: Success!		

Regular Weekly Visits

After the initial medical assessment, patient visits will be more brief, but equally important in order to ensure patients are achieving optimal health while continuing on the program.

Areas Covered:

1. Weight check
2. Blood pressure
3. Lab results
4. Potential side effects to be aware of
5. Medication adjustments
6. Reviewing the dashboard
7. Reinforcing delivery of educational topic
8. Complete progress note

1. Weight Check

After the initial visit, patients will continue to come for office visits, which occur weekly in the first month and bi-weekly in the second and subsequent months of the program. The main purpose of these visits is to ensure optimal patient health as well as maintain patient accountability in the program.

During the weight check, a health care provider or other practice staff member will take the patients weight (following the suggested guidelines outlined above) and enter the information into the Progress Notes section of the Provider Dashboard.

Most patients can expect to lose more weight in the first week or two of the diet due to the release of water from the body. Unless the patient is symptomatic, this should not be concerning. Significant variation of weight loss may be due to a variety of circumstances such as fluid fluctuations, dramatic changes in physical activity, medication changes or deviations from the diet. The impact of medications such as steroids, diuretics, and antidepressants should be considered when weight loss is not as expected.

Also, a very abrupt increase in exercise may result in less weight loss due to fluid retention. Patients need to be warned about this possibility so that they are not overly discouraged if the scale doesn't reflect the effort and compliance to the diet. That being said, compliance to the diet is the key component to successful weight loss.

If both the patient and the health care provider are both using the online tracking tools, it will help identify any discrepancies between the diet prescription and the patients' adherence to it.

2. Blood Pressure

Blood pressure should be taken at office visits using the same arm and an appropriate cuff. Most individuals will experience a significant decrease in systolic and diastolic blood pressure levels. It is for this reason that patients taking blood pressure medication need to be monitored carefully and have medications adjusted as necessary.

3. Lab Results

Baseline labs results will need to be reviewed and abnormal levels treated as appropriate. We recommend that a comprehensive metabolic panel, uric acid and a lipid panel be repeated every 6 weeks after the initial baseline labs are taken.

Follow-up EKGs are repeated at the discretion of the physician based on the medical need.

For additional monitoring guidelines, please refer to ***Section 3: Medical Training & Supervision.***

4. Potential side effects to be aware of

The majority of issues reported by patients on a VLCD are mild and easily managed. The most commonly reported side effects can be prevented with adequate hydration and compliance to the dietary protocol. Symptoms that may be reported include: lightheadedness and dizziness, bowel changes such as constipation or diarrhea and fatigue, muscle cramps, hair loss, gallbladder attacks, cold intolerance, hunger, halitosis, libido changes and changes in menstrual cycle, bruising, symptomatic hypoglycemia and neurological symptoms.

Please refer to ***Section 3: Medical Training & Supervision*** *for more details for how to manage these potential side effects.*

5. Medication adjustments

Physicians should be particularly attuned to the possible need to adjust medications that are directly impacted by weight loss such as diabetes medication, hypertension medication and lipid lowering medications.

The physician will need to review a patient's medication regime in relation to how the diet may affect the blood levels and result in side effects. The physician will determine changes in the type, dosage and/or frequency of medication and the need for laboratory testing to monitor drug level.

a) Medications to discontinue

1. Diuretics

b) Medications that may require dosage adjustments

1. anti-angina mediation
2. antihypertensives
3. Coumadin
4. Depakote
5. Digoxin
6. Dilantin/Tegretol
7. Insulin *
8. Lipid lowering Agents
9. Lithium
10. Oral hypoglycemic
11. Quinidine
12. Thyroid medications
13. Tricyclic antidepressnats

MONTH 2 & ONGOING

In the second and ongoing months of the program, office visits become bi-weekly and follow the same format as the regular weekly visits in the first month. During the entire course of the program, patients will have unlimited access to Advisors for support on using the Web tools. In addition, Advisors will proactively engage patients to maximize their participation in the program by providing positive reinforcement and encouraging activity.

**Insulin dependent diabetics will need to be closely monitored while on this program. For additional information on managing this special population, please see Section 3: Medical Training and Supervision.*

Section 2: Medical Training & Supervision

INITIAL VISIT

Phase 1: VLCD Contraindications

1. Pregnancy and Lactation

Nutritional requirements are increased during pregnancy and lactation. Phase 1 of the SetPoint JumpStart (VLCD) cannot meet these increased requirements. These patients however may be good candidates to start the program in Phase 3: Success for more gradual weight loss results.

2. Children under 18 years

For children who are still growing, very low energy diets should be avoided.

3. Porphyria

Most porphyrics who experience repeated attacks find weight control a problem. Fasting should be avoided in people who have porphyria. Fasting or extreme dieting can provoke an acute attack.

4. Advanced Hepatic Disease

Persons with advanced liver disease (cirrhosis) or active hepatitis should not be started on Phase 1 of the Program.

5. Recent Myocardial Infarction

Refer these patients to a cardiologist to determine suitability for calorie restriction.

Precautions

1. Chronic Hepatic Disease

Patients with markedly elevated LFT (at more than twice normal ranges) should be started on at 1000 kcal Transition phase and LFT should be monitored weekly if there is a concern about the levels. If LFT are stable or decline in the first 2 weeks continue with Phase 1: VLCD and continue to monitor LFT every week. If LFT rise after the first 2 weeks, return to the modified 1000 kcal protocol and continue to monitor.

2. Pancreatitis

Gallbladder problems may be associated with pancreatitis and/or cholangitis. In patients with a suspected history of cholecystitis or gallstones, the potential for the development of pancreatitis must be considered and reviewed with the patient. Isolated acute pancreatitis has been reported only rarely during weight reduction; however, with a patient complaint of severe abdominal pain and/or elevated amylase gamma glutamyl transpeptidase, pancreatitis and/or cholangitis should be considered and, if confirmed, the patient should be advised to postpone weight reduction until the condition is treated and resolved.

3. Advancing Renal Disease

Use careful medical judgment when prescribing weight loss for patients with advancing renal disease (BUN>40). Watch for progression of uremia secondary to dehydration or inability to handle protein load. Fluid restriction must be checked.

4. Type 1 Diabetes

Patients with Type I diabetes and a history of ketoacidosis are usually not obese. However, overweight and obese Type 1 diabetics can benefit from the effect on comorbidities that rapid weight loss can induce. If this treatment is undertaken, supervision from an endocrinologist or a diabetic educator experienced in the use of very low energy diets is essential. Blood glucose levels will need to be monitored closely throughout the first few days as levels fall.

The patient will require instruction to reduce insulin dosage and to manage potential hypoglycemia. It may be necessary to modify the dietary prescription to increase the number of products per day. Monthly blood chemistry testing is useful to assess any change in electrolytes. A similar pattern of supervision is necessary for overweight or obese Type 2 diabetics using insulin medication.

5. Type 2 Diabetes using Medication

For Type 2 Diabetic patients using medication, it may be necessary to make adjustments to the medication levels to avoid hypoglycemia. There are two classes of hypoglycemic medication; those that increase circulating insulin (sulphonylureas and insulin) and those that do not (metformin, rosiglitazone, pioglitazone and acarbose). If the patient is on an insulin-raising medication there will be a risk of hypoglycemia so it will be important to reduce the dose of sulphonylureas or insulin when starting a VLCD. The aim will be to stop these medications if possible. Consideration can be given to ceasing acarbose since there is only a small amount of carbohydrate in Physicians Protein Smoothies™ products. While the requirements of each patient will need to be assessed individually, a general guide is to halve the dose of insulin or sulphonylurea and to ask the patient to monitor blood glucose more carefully over the first few days. Warn the patient about the risk of hypoglycemia and if necessary review the symptoms to be expected. Further adjustments are then made to the medication based on the resulting blood glucose values. To facilitate careful monitoring it may be advisable to start the VLCD phase on a weekend.

6. Acute Cerebrovascular or Cardiovascular Disease

Patients who have had a recent (within 3 months) acute myocardial infarction or unstable angina, as well as patients with recent (3-6 months) recurrent stroke or TIAs, should not be admitted to a weight loss program until the condition has stabilized.
Medical care and dietary recommendations should be coordinated with the primary physician, cardiologist, and neurologist, if appropriate.

7. Overt Psychosis

Individuals diagnosed with psychosis should only proceed with a very low energy diet under the guidance of their medical practitioner. The medical practitioner must weigh up the benefits versus the risks. The effects of medications used to treat psychosis may be altered when the patient is in a ketotic/acidotic condition. The psychotic state may lead to inappropriate and/or unreliable use of the very low energy diet.

8. Elderly

The VLCD phase is not recommended for use in persons over the age of 65 years, as metabolic and physiologic adaptations to intensive diets are decreased in the elderly. However under conditions in which rapid weight loss is considered to be life saving a modified VLCD may be prescribed under medical supervision.

9. Women

MENSTRUAL CYCLE CHANGES – Women may experience a variety of changes in their menstrual cycle during weight loss. Cycles may resume with weight loss and generally normalize following re-feeding.
FERTILITY – Women previously infertile (due to polycystic ovarian syndrome) may ovulate and become fertile while on a weight loss program. Women should be informed and should take appropriate birth-control precautions. Women who are trying to lose weight to improve their fertility, should be advised to take a daily fish oil supplementation to ensure sufficient intake of essential fatty acids.
DIAPHRAGM USAGE – Patients who are using a diaphragm for birth control may need to be referred to their OB/GYN for periodic checks on the fit, since fit may change as the patient loses weight.

10. Medication Monitoring

Individuals receiving medication for Type 2 diabetes, hypertension, hyperlipidemia or those on lithium therapy may need a reduction in dose or withdrawal from treatment whilst undergoing very low energy diet treatment. Such individuals should be monitored carefully in the first few weeks of treatment.

11. Patient Monitoring

Careful monitoring is required in patients with a history of hepatic or renal disease.

Screen for gallbladder disease before initiating.

12. Alcohol and caffeine

Both alcohol and caffeine are diuretics, which can cause fluid loss from the body.

Ensuring adequate fluid intake while on the program is important as dehydration can lead to dizziness and fatigue. It is important to drink an extra 2 liters of water or other calorie free liquids each day during the program. Alcohol also contains extra calories, which will make weight loss slower. Additionally, even a small serving of alcohol will "jump to the front of the line" metabolically, and abort fat burning. A small amount of caffeine can be included in the form of 1–2 cups of coffee per day (ideally black coffee).

13. BMI >35

Patients with a BMI >35 should be monitored closely and an additional serving may be required to meet daily protein requirements.

Initialrapid weight loss is considered to be life saving a modified VLCD may be prescribed under medical supervision.

INITIAL VISIT

VLCD Monitoring Guidelines

High Medical Risk:

1. BMI ≥ 35 or < 35 with co-morbid conditions
2. Taking any prescribed medications requiring adjustment
3. More than 50 years of age
4. Manifesting CV risk factors
5. Abnormal baseline labs which change with weight loss

Low Medical Risk:

1. BMI < 35 with no co-morbid conditions
2. No prescription medications
3. Less than 50 years of age
4. No known CV risk factors
5. No abnormal baseline labs

INITIAL ASSESSMENT	High Risk	Low Risk
Medical history	✓	✓
Informed Consent	✓	✓
Blood tests: complete blood count with differential and platelet count. Comp. Metabolic Panel, CK, Uric Acid, Lipid Panel, TSH, A1C if patient has diabetes	✓	✓
Urinalysis: Microalbuminuria, ketones, pH, etc.	✓	As appropriate
12 lead resting Electrocardiogram (EKS) with computed QTc interval	✓	As appropriate
Height. Weight. BMI. Waist Circumference. Overall Risk of Disease	✓	✓
Physical ecamination conducted heart, lung, abdomen, extremities	✓	✓
VLCD PAHSE (12 weeks)		
Blood tests	Every 6 weeks	Every 12 weeks
Electrolytes	Every 4-6 weeks	As appropriate
EKG	Every 50 lbs lost/week 12	As appropriate
Medical Visits: Weight, pulse, BP	Each week for 4 weeks, then every 2 weeks	Each week for 4 weeks, then every 2 weeks
TRANSITION PHASE (4-8 week)		
Blood tests	Every 6 weeks	As appropriate
Electrolytes	As appropriate	As appropriate
Medical Visits: Weight, pulse, BP	Every 2 weeks	Every 2 weeks
MAINTENANCE PHASE (ongoing)		
Blood tests	As appropriate	As appropriate
Electrolytes	As appropriate	As appropriate
Medical Visits: Weight, pulse, BP	As appropriate	As appropriate

Medications

Although comprehensive, this is not an exhaustive list. Medical judgment should be applied whenever initiating OTC or prescription medications

No interaction

Minor tranquilizers, antibiotics, anti-emetics, anti-diarrhoea agents, antacids, oral contraceptives, oestrogen for the prevention of osteoporosis and antihistamines. These can all be used normally.

Insulin

For diabetics who are insulin dependent, special considerations may need be taken.
See recommendations for diabetics on insulin below.

Hypotension

Hypotension is most common in first weeks of very low energy diet therapy.

Diuretics: Normally, these need to be reduced markedly at the start of modified fasting to avoid sodium and water depletion.

Anti-hypertensive agents: Doses will usually need to be reduced or stopped. In some large series, these drugs were routinely stopped at the start of modified fasting. Only rarely did they have to be restarted. It is important to watch closely for dangerous hypotension in the first few weeks if patients remain on anti-hypertensive agents. Major tranquilizers and narcotic analgesics:

Hypoglycemia

Hypoglycemia is most common in first weeks of very low energy diet therapy. Oral hypoglycemic agents and insulin: These will often need to be reduced or stopped and the patient should be alert for hypoglycemia. These drugs have been routinely stopped at the start of a very low energy diet program. Reduction or elimination of need for medication is not uncommon.

Other medications to review

Lithium: Patients on lithium maintenance may experience changes in serum lithium levels due to sodium depletion and renal retention of lithium. Monitor lithium levels weekly, then bimonthly. Lithium may interfere with thyroid function. Thyroid function should be checked periodically

General anesthesia: If required in an emergency, this should be preceded by intravenous saline, 5% dextrose and potassium replacement

Corticosteroids: Chronic use of steroids (more than 20mg daily of prednisone or its equivalent) must be evaluated carefully because of the tendency to nitrogen wastage caused by the drugs. Acute short-term steroid therapy of one to two weeks duration may not be a problem. If in your assessment the risk/benefit ratio favors treatment, these patients may require more protein to counteract potential catabolic effects of the steroid therapy. Chronic use of drugs with GI side effects: Drugs with potent GI side effects (for example, non-steroidal anti-inflammatory drugs [NSAIDs] and steroids) need to be
evaluated. If food had a significant buffering effect, a person may require antacids, cimetidine, enteric-coated aspirin to prevent GI side-effects.

Drugs with a narrow therapeutic index:
In medication where there is a narrow therapeutic index (e.g. warfarin) caution should be exercised.

The medications effect may need to be considered against their benefits to the patient. In some cases, alternative medications with less impact on weight gain may be available. Medications which may have an adverse effect on weight loss, i.e. either increase hunger or decrease energy expenditure.

- Benzodiazepines
- Corticosteroids

- Antipsychotics
- Tricyclic antidepressants AND MAO Inhibitors
- Anti-convulsants (valproate, gabapentin, carbamazepine)
- Anti-diabetic agents (sulphonylureas, insulin, thiazolidinediones)

Recommendations for Diabetics on Insulin

1. Patients need to commit to self-monitoring blood glucose a minimum of 4 times/ day when commencing the diet. The frequency of self-monitoring blood glucose can be reduced over time if patient is managing blood sugars within target range.

2. Remind patients of the importance of taking their full prescription of Physicians Protein Smoothies™ and to spread intake of smoothies throughout the day. For example, consuming a smoothie every 3 hours during waking hours may be suggested.

3. Patients with FBS≥ 350 should be treated for diabetes management prior starting a weight loss diet.

4. Patients with FBS between 200-360 mg/dl, on insulin therapy and starting the VLCD should have their insulin reduced by 25% when starting the diet.

5. Patients with FBS < 200 mgs/dl and on insulin therapy should have their insulin reduced by 50% when starting the diet.

6. Patients should contact the medical staff for blood glucose levels < 100 mg/dl or if they experience 3 or more readings in excess of 250 mg/dl.

7. Insulin should be reduced by 10-15% for blood sugars < 100 to prevent hypoglycemia.

8. Patients on insulin pumps generally adhere to the same rules as patients taking insulin.

9. An initial reduction of the basal rate by 25% with further

10. For patients on insulin pumps, the meal boluses are smaller due to decreased carbohydrate intake while on Phase 1: VLCD protocol.

11. Goals of normal glucose values in pump patients need to be liberalized or adjusted upwards to avoid hypoglycemia.

Diabetic "sick day" management

Patients unable to comply to the Phase 1: VLCD guidelines due to illness (can't take in sufficient amount of Physicians Protein Smoothies™ and/or water) need to be assessed by medical staff. With the goal of preventing ketosis and dehydration, more frequent SMBG and medicine adjustments may be needed.

Oral agent management

1. Sulfonylureas: Glyburide, Glipizide, Glimepiride: Continue if pre-meal and FBS >200 mg/dl. Discontinue when pre-meal and FBS < 200 mg/dl. If baseline glucose level is < 120 mg/dl at screening discontinue medication.

2. Meglitinides: same as above.

3. Biguanides: metformin, glucophage, glucophage R, fortamet, glumetza, Riomet: Patients on meformin with serum creatinine >1.3 should discontinue the drug before starting diet. Patients must monitor blood glucose at least 2 times/day. Patients on metformin only can typically monitor less frequently due to low risk of hypoglycemia.

4. Thiazolidinediones: Actos, Avandia: Should be gradually reduced for patients with pre meal glucose levels < 120 mgs/dl. Patients must monitor blood glucose at least 2 times/day.

5. GLP-1 receptor agonists: Byetta, Victoza, Exenatide extended-release: Discontinue when starting Phase 1: VLCD if taken with insulin. If taken with sulfonyurea, discontinue the sulfonyurea. Continue if patient has been taking 10 mcg for at least 30 days w/o

6. Pramlintide - Amylin, Symlin: Recommend discontinuation at start of diet due to risk of hypoglycemia. Do not start during Phase 1: VLCD due to risk of hypoglycemia, nausea and vomiting.

7. Dipeptidyl Pepdidase: 4 inhibitors (Januvia, Onglyza, Tadjenta) Can continue as monotherapy, or in combination with Metformin, Avandia or Actos If used in combination with sulfonylurea, discontinue the sulfonyurea. Discontinue at onset of diet if used in combination with insulin.

FOLLOW UP VISITS

Potential Side Effects

Common physiological changes may occur during weight loss. Some of these changes may need to be monitored. Very low calorie diet protocols (800kal/day) have been a common method of weight loss for the last 40 years and with the correct medical supervision have resulted minimal adverse reactions or consequences.

Most side effects are typically very mild and easily managed, with the majority prevented by ensuring the patient is compliant to the diet protocol, including necessary hydration.

Some of the common initial transient effects include:

Bruising
A very uncommon side effect is an increased incidence of bruising. When it occurs, it is a transient effect and best addressed by giving Vitamin C supplements in amounts up to 1000 mgs/day.

Sensitivity to cold
Patients may find that they are more intolerant to cold temperatures due to the reduction in body fat caused by the weight loss. However, the main reason for the sensitivity to cold is decreased dietary thermogenesis due to reduced calorie intake. Patients should

Temporary hair loss

Some hair loss can occur when patients lose a significant amount of weight or are adhering to the VLCD for an extended period of time. The exact reason for the hair loss is unknown but the patient should be told that this hair loss is temporary, won't result in baldness and is not indicative of a nutritional deficiency.

Postural hypotension

The feeling of lightheadedness and dizziness can most often be addressed by ensuring that the patient consumes their full complement of smoothies as well as drinking an additional 2-3 quarts or non-caloric fluids/day. If the symptoms persist, and the patient doesn't have hypertension, the patient should be encouraged to drink ½ cup of bouillon two to three times /day. Patients need to be reminded that if they are increasing their physical activity or in very hot weather, they should be drinking even more than the recommended 2-3 quarts of water/day.

Fatigue

Again, adequate hydration can decrease the feeling of fatigue. If patient is experiencing low blood pressure then the addition of sodium through intake of a ½ cup of bouillon two to three times/day may be indicated.

Diarrhea

Diarrhea can be caused by a lactose tolerance, intake of sugar substitutes, or an infectious agent. The Physicians Protein Smoothies™ contain a small amount of lactose (.35 grams/serving) which can be tolerated by many individuals who cannot tolerate larger amounts of lactose. If a patient experiences diarrhea shortly after consuming one of the Physicians Protein Smoothies™, using Lactaid tablets immediately piror to drinking the can help determine if the diarrhea is due to lactose tolerance.

If the diarrhea doesn't resolve with the trial of lactaid, other causes of flatus, cramping and diarrhea such as consumption of sorbitol or xylitol should be investigated. If diarrhea occurs later in the diet, infectious causes should be considered. Metamucil, Immodium A-D or Kaopectate may be beneficial in these cases. Whatever the cause, patients experiencing diarrhea should be reminded to continue drinking fluids to avoid dehydration.

Constipation

Because of the fiber content in Physicians Protein Smoothies™, patients typically do not have issues with constipation. Since the patient will be consuming much less food overall when on the Phase 1: VLCD, they should expect fewer bowel movements per week. If a patient does experience constipation, verify that they are consuming the appropriate number of smoothies/day and the minimum of 2-3 quarts of water/day. If constipation occurs, it can be treated with Milk of Magnesia, Metamucil, Citrucel, Benefiber or a comparable product.

Muscle cramps

Muscle cramps are not common and typically can be treated by increasing fluid intake. Potential causes of muscle cramps include a sudden increase in physical activity, dehydration, low sodium or rarely, low potassium. Patients can be directed to do stretching exercises, increase fluid intake, and/or increase sodium intake through the use of bouillon. If a patient's bloodwork reveals low potassium, a potassium prescription may be indicated.

Halitosis

Since the Physicians Protein Smoothies™ used contain carbohydrates and only result in a mildly ketotic diet, bad breath should not be as problematic. Patients should be encouraged to increase fluid intake and/or use breath spray. Increased flossing and brushing can be helpful in keeping gums and teeth healthy.

Hunger

Hunger typically occurs only in the first stages of the VLCD, when the patient is adjusting to the new diet. Encouraging the patient to assess whether it is head hunger or physiological hunger can be a first step in the patient's path to self-awareness.

Libido Changes

Patients' libido may be altered in either direction. This is typically a temporary change related to diet. Ultimately, weight loss can prove to be a positive factor in libido.

Menstrual disturbances

Weight loss frequently causes changes in menstrual function but does not result in longterm problems after the diet is liberalized. Female patients should have the date of their last menstrual period documented in the medical record and pregnancy tests taken as appropriate.

Neurological symptoms

Numbness, focal weakness or memory loss after significant weight loss needs to be evaluated carefully. Prolonged crossing of knees after weight loss has sometimes resulted in temporary peroneal nerve palsy.

<u>Other rare side effects may include:</u>

GALLSTONES

The risk for cholelithiasis is significantly higher in overweight and obese individuals. Gallstone formation can be induced through the rapid weight loss that occurs with a VLCD. This occurs when the diet contains negligible amounts of fat. The daily addition of 5ml (one teaspoon) of vegetable oil stimulates the emptying of the gallbladder and may help prevent the formation of gallstones.
Also, the use of urosodeoxycholic acid (Actigall) can help prevent the formation of gallstones and subsequent gallbladder symptoms. As patients begin to liberalize their diets to include different and higher fat foods, pre-disposed individuals may experience gallbladder

symptoms. Patients should be warned against abruptly increasing fat intake during the Phase 1: VLCD or as they transition to the more liberal stages of the program.

SERUM *URIC ACID*

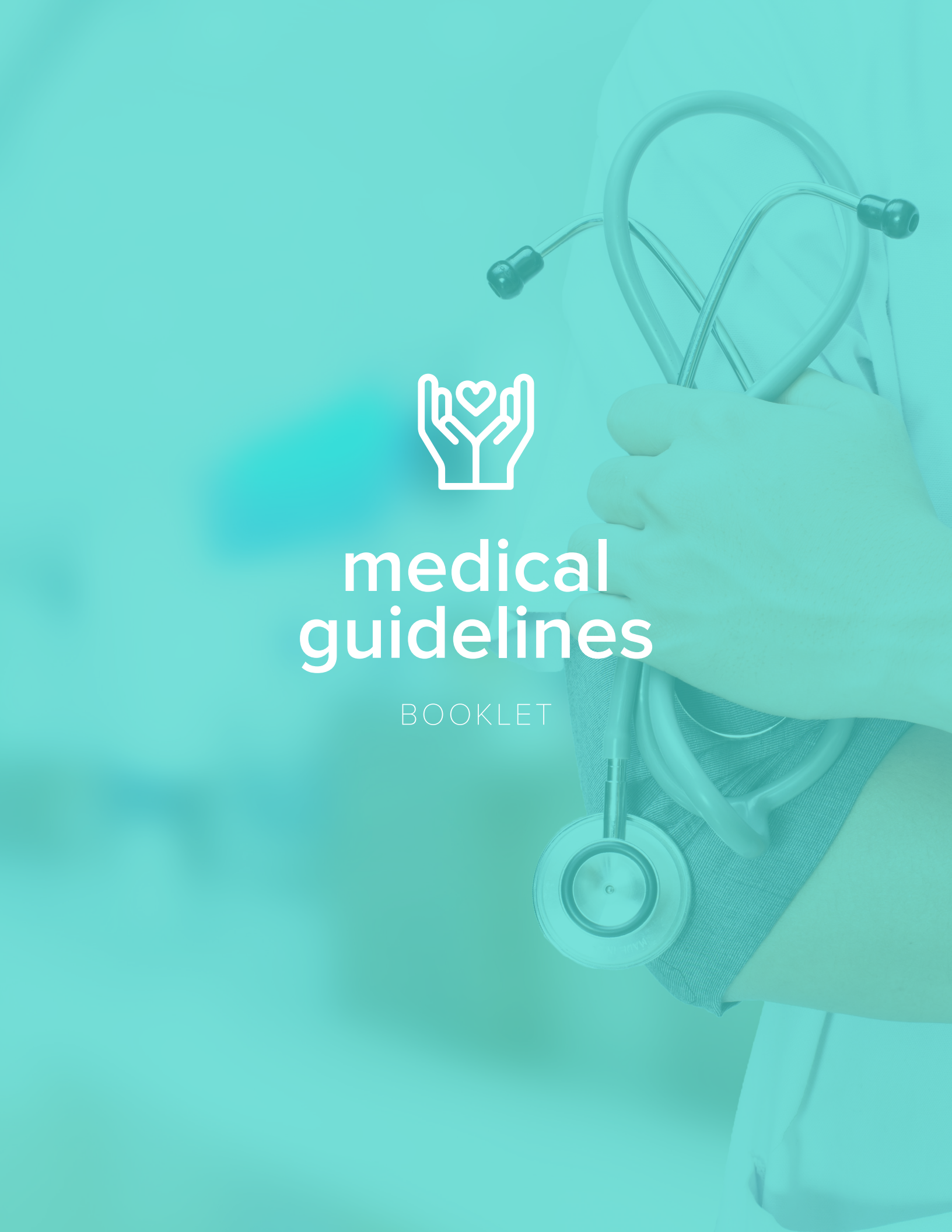
In most patients, the uric acid level decreases. However, in the predisposed individual, rapid weight loss occasionally leads to higher serum uric acid levels and might precipitate an acute attack of gout in a predisposed individual. This may be ameliorated by ensuring adequate fluid intake, but in severe cases therapy such as allopurinol may be indicated.

ELECTROLYTES

Although the products contain adequate electrolytes for the needs of most individuals, some individuals may become hyponatremic or hypokalemic, especially if they are receiving diuretic therapy. In such circumstances, electrolyte supplements may be required.

LIVER ENZYMES

Transient elevations of hepatocellular enzymes may occur through the active VLCD treatment phase, but progressive elevation beyond three times the upper limit is abnormal and unusual. Elevations of liver enzyme values (SGOT, SGPT, ALT, GGT) occur in a significant number of morbidly obese patients. Sometimes such elevations are present at baseline and decrease to normal during weight loss. Isolated elevations of hepatocellular enzymes and absence of significant elevations of bilirubin or alkaline phophatase or findings of acute disease may not require further investigation or changes in dietary protocol. Significant elevation of bilirubin and/or alkaline phophatase and gamma glutamyl transpeptidase (GGT) with a progressive elevation of hepatocellular enzymes suggest intercurrent hepatic disease, such as hepatitis or pancreatitis and must be investigated.



medical guidelines

BOOKLET