FORMULITE

Medical Weight Loss Protocol

A guide for health professionals caring for patients with obesity

Written by Dr. Fiona Tsuey Hung Lee (MBBS, FRACP, MD)
and Sally-Anne Livock APD

Edited and Compiled by Glennis Winnett

Formulite
info@formulite.com.au
www.formulite.com.au

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FORMULITE VERY LOW ENERGY DIET MEDICAL PROTOCOL FOR WEIGHT LOSS

The Formulite Very Low Energy Diet Medical Protocol is intended to support health care professionals caring for patients with obesity. The Protocol identifies specific nutritional issues and guides health care professionals about the best use of Formulite products for patients who may benefit from using a VLED.

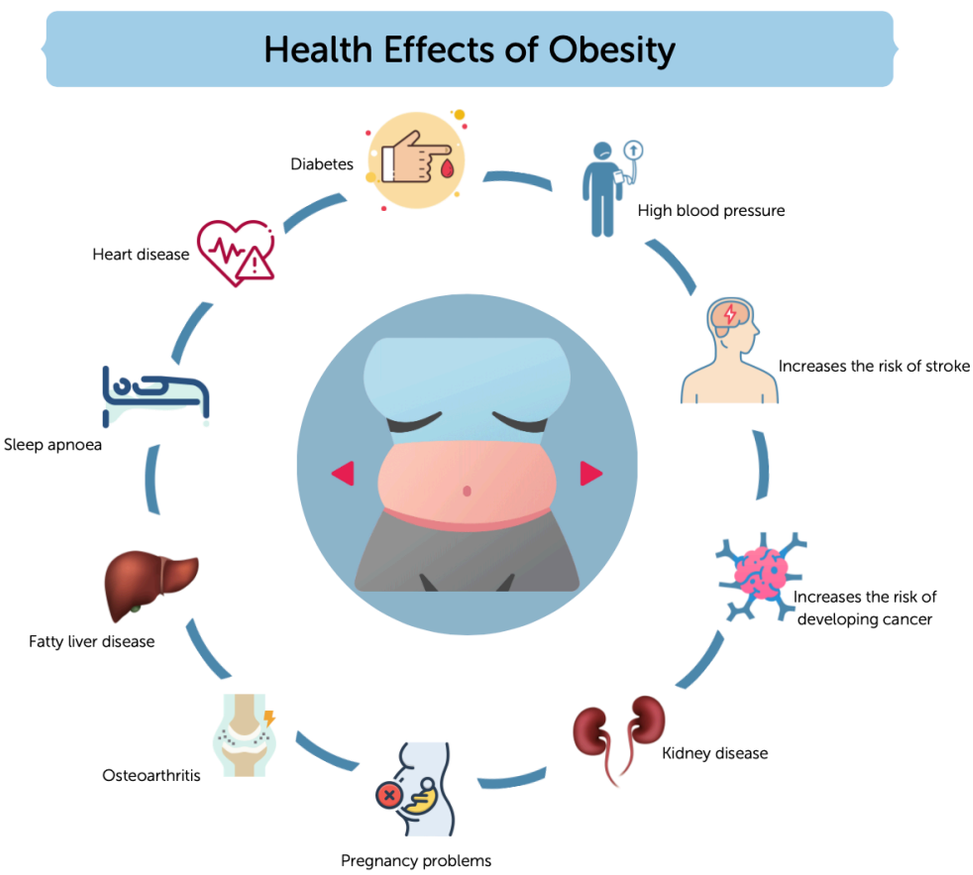
CONTENTS

INTRODUCTION

The prevalence of obesity has increased to epidemic proportions. Obesity has reached "crisis level" as stated in a recent position paper from the Australian Medical Association (AMA).

The Australian Bureau of statistics reports that 67% of Australians were overweight or obese in 2017 compared with 63.4% in 2014-2015. This rise in overweight and obesity, as stated by the AMA, has resulted in the current "Obesity crisis".

It has been estimated that obesity has a greater negative impact on quality of life than 20 years of ageing. The extent of this impact persists after adjusting for demographics, medical conditions and health habits.



Chronic diseases associated with obesity include type 2 diabetes, cardiovascular disease and cancer (in particular endometrial, colorectal, oesophageal, renal and breast cancer). Weight loss has been shown to result in marked medical benefits but is often perceived as difficult in the primary care setting. The very low energy diet (VLED) is well suited for health professionals to implement in their practice.

Diabetes is increasing in parallel with obesity. Today, 1.8 million Australians have diabetes. Additionally, there are more than 4,400 amputations every year as a result of diabetes health related complications. The total cost of the impact of diabetes in Australia is estimated to be over $14.6 billion annually (Australian Bureau of Statistics).

MALNUTRITION OF OBESITY

Nutritional Status

As well as metabolic and disease complications, obesity is directly associated with significant rates of malnutrition, where it has been found that up to 80% of patients are in a compromised nutritional state (1,2).

Nutrient-poor food choices and chronic dieting cycles can contribute to this state of malnutrition. Additionally, side effects of medications to treat comorbidities may impact on nutrition as well as other environmental and lifestyle factors. Patient malnutrition is often masked by an excess intake of energy.

Studies of obese patients show the following incidence of malnutrition (1,3).

Nutrient	% Obese patients' deficiency
Iron	Up to 45%
Vitamin B12	2-18%
Folate	54%
Vitamin D	65-90%
Thiamin	20%
Zinc	20%
Vitamin A	14%

Nutritional screening should be completed to allow for dietary corrections to begin. Refer to assessment for screening details.

Protein Status

Obese patients have higher protein requirements than the general population due to a combination of the following factors:

1) Sarcopenic Obesity

Sarcopenia is a complex multifactorial condition influenced by nutrition, physical activity, comorbidities and psychosocial factors. Sarcopenia is identified as low levels of muscle strength, muscle performance and skeletal muscle mass. Loss of mass, performance and strength, impact ability to exercise, can impede tasks of daily living, and can increase risk of falls - all impacting quality of life.

Like osteoporosis, the changes that precipitate sarcopenia can occur early during the fourth and fifth decade of life. Sarcopenia is facilitated by an inactive lifestyle, catabolic stressors including acute or chronic illness, or injury, inflammation, low dietary protein intake, and poor nutrition - often all present in the obese population (4).

2) NAFLD (Non-Alcoholic Fatty Liver Disease) occurs in up to 90% of surgical patients and is also associated with increased protein requirements (5). It is important to consider the increased protein requirements of obese patients when formulating nutrition plans.

The points of significance are:

- If low energy diets are not correctly formulated patients may be protein deficit
- There is strong evidence that lean tissue loss can be attenuated by diets higher in protein, compared to those with a lower protein intake (6,7,8)
- Low energy diets require **high biological value** protein at up to **1.5 g protein/kg/day** to limit lean muscle loss (4,8,9)

WHAT IS A VERY LOW ENERGY DIET?

Definition

A VLED is an intensive weight loss program consisting of nutritionally complete meal replacements, replacing 2-3 meals a day. This results in a significant energy deficit and rapid weight loss. Weight loss of approximately 1-2 kg per week can occur but will vary greatly depending on baseline weight, sex and activity level. Many meal replacements are available but not all will be nutritionally complete.

Formulite is a specifically formulated meal replacement, meeting the rigorous nutritional requirements of the Food Standards Code for formulated meal replacements.

The VLED is not only low calorie (<800kcal/day) but has low carbohydrate content of approximately <50g/day. By reducing carbohydrate intake sufficiently beta-oxidation of free fatty acids in the liver occurs producing ketone bodies; b-hydroxybutyrate, acetoacetate and acetone. Ketosis is induced, which reduces appetite by blocking the compensatory changes in appetite regulating hormones, such as ghrelin and cholecystokinin, that usually occur with weight loss (10,11).

MEDICAL PROTOCOL

Who Is Suitable For The Program?

- BMI > 30 kg/m2 (4)
- Waist circumference of greater than 88cm in women and 102cm in men
- Well-motivated
- History of failure with conventional weight loss methods
- For rapid weight loss prior to elective surgery
- To allow for increased mobility in patients with joint pain and arthritis
- Presence of a medical condition that would improve rapidly with rapid weight loss, such as obstructive sleep apnoea, hypertension, hepatic steatosis, dyslipidaemia and type 2 diabetes mellitus

FORMULITE PROGRAM

The duration of the program can vary between 3-12 months and depends on the patient's tolerance of the diet and their weight loss goal. Individual protein requirements should be calculated at each stage and a program designed to meet these requirements. See page 7, calculation of protein requirements. Most patients start with stage 1 and move through the stages as guided by their medical practitioner or dietitian.

Stage 1 <800 Calories/day
RAPID PROGRAM

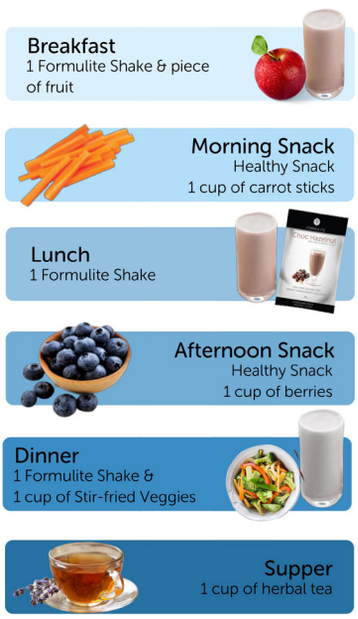
1. 3 Formulite shakes/day + low starch/carbohydrate snacks from allowed chart.

OR

2. 2 Formulite shakes/day:

1 Formulite shake + 1 Formulite shake with 1 cup low starch vegetables + 1 low carbohydrate meal (2 serves lean protein and 1 cup low starch vegetables).

3 meal replacements per day can be difficult for many people to adhere to long term and the second option with 2 meal replacements per day may be easier to maintain and allows patients to eat 1 meal with the family.

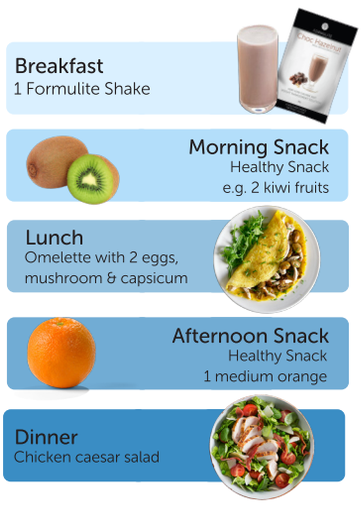


Stage 2 <1000 Calories/day
STANDARD PROGRAM

1 Formulite shake & small serve berries + 1 Formulite shake + low starch/carb snacks + 1 meal (2 serves lean protein and 1 cup low starch vegetables). **Extras/snacks:** 1 fruit and 1 low fat dairy.

Stage 3 <1200 calories/ day
MAINTENANCE PROGRAM

Regular food or continue with 1 meal replacement per day long term which is often quite acceptable and convenient especially for patients with busy lives.



Essential Components of the VLED

In order to achieve effective weight loss and ketosis it is important to avoid carbohydrates, sugar and alcohol and choose foods from the allowed foods list only.

FOODS TO INCLUDE

1. Formulite shakes

2. 2L of water daily

3. Allowed foods and drinks

The following list includes food that is allowed which provide daily micronutrient requirements in addition to dietary fibre, variety and snack options.

Vegetables & Salads

asparagus
bamboo shoots
bean sprouts
beans, green
beetroot
basil
bok choy
broccoli
Brussel sprouts
cabbage
capsicum
cauliflower
carrot
celery
choko
choy sum
cucumber
eggplant
endive
garlic
ginger
leeks
lettuce
marrow
mushrooms
onion
spring onion
pumpkin
radish
radicchio
rocket
sauerkraut
silverbeet
spinach
tomato
zucchini

Condiments

fresh or dried spices
fresh or dried herbs
chilli sauce (not sweet chilli)
fresh or dried herbs
soy sauce (not other e.g. oyster)
vinegars - balsamic (not reduced), apple cider vinegar
garlic
ginger
lemongrass
lemon juice
lime juice
vegemite
promite
mustard
curry powder or paste (not sauces)
stock or clear broth

Beverages

soda water
diet cordials
miso soup
mineral water
spring water
diet soft drink - but encouraged to limit
coffee, 2/day (<30ml milk)

Fruit

1/2 cup of berries

Others

diet jelly
sugar free gum

4. Essential Fats

Help reduce the risk of gall bladder complications (12).
Sources of essential fats - 1 choice daily recommended from the following:

- 10 (approx. 15 g) raw nuts
- 1/4 medium avocado
- 5 ml oil (1 teaspoon)

5. Additional Protein

may be used if the 3-shake program does not meet protein needs or to replace a shake in a combination meal and shake program.

Examples of food protein sources:

- 100 g lean beef (approx. 65 g cooked) = 25 g protein
- 100 g poultry (approx. 80 g cooked) = 26 g protein
- 120 g fish (approx. 100 g cooked) = 24 g protein
- 2 eggs = 12 g protein
- Tofu 130 g = 15.5 g protein
- 160 g natural or high protein (low carb) yoghurt = protein 10 g
- 1 cup milk = 9 g protein

FOODS TO AVOID

Carbohydrates	Drinks	Vegetables	Sugars	Alcohol
bread, rice, pasta, all other grains, fruits not on extras list, vegetables not on above tables, crackers, legumes	soft drink cordials & juices milk based products	potato sweet potato corn	confectionery chocolate	all alcohol

Calculation of Protein Requirements

As discussed, patients with BMI >30 often have high protein requirements. It is vital that the VLED adequately meets protein needs. Therefore, protein requirements must be accurately and individually calculated (see protein calculations below).

Calculation of protein requirements will determine the number of shakes/day as well as any additional foods required to meet protein needs.

As with any obese population, energy calculations should be made using ADJUSTED IDEAL BODY WEIGHT AIBW (13).

This takes into account the 25% excess metabolically active tissue, in an obese individual.

ABW=Actual body weight
IBW = Ideal body weight (weight at BMI 25)

AIBW = (Actual weight - IBW) x 0.25 + IBW
E.g. Actual weight 135 kg height 168 cm weight at BMI 25 = 71 kg

AIBW = ((135-71) x 0.25) + 71
= (64 x 0.25) + 71
= 71+16
= 87

Protein Requirements = 87 g/day
(1 g protein/kg AIBW/day)

Current guidelines vary but recommend 0.75-1 g protein/kg and studies show protein >0.8g/kg/IBW is required to prevent excess loss of lean tissue during a VLED (14,7,3).

We recommend at least 1-1.5 g protein/kg AIBW/day, to attenuate lean muscle loss (7,9,15,16) and calculations should be made based upon individual patient requirements, taking into account factors discussed in Protein Status pages.

FORMULITE AND PROTEIN REQUIREMENTS

The Formulite 3 shakes/day program (stage 1) is currently the only VLED on the Australian market with a 3 product/day program meeting protein requirements for the majority of our obese population (Aug 2020).

Formulite - 3 shakes/day provides 105g protein

Other most popular VLED used in Australia - 3 shakes per day provides 60 g protein.

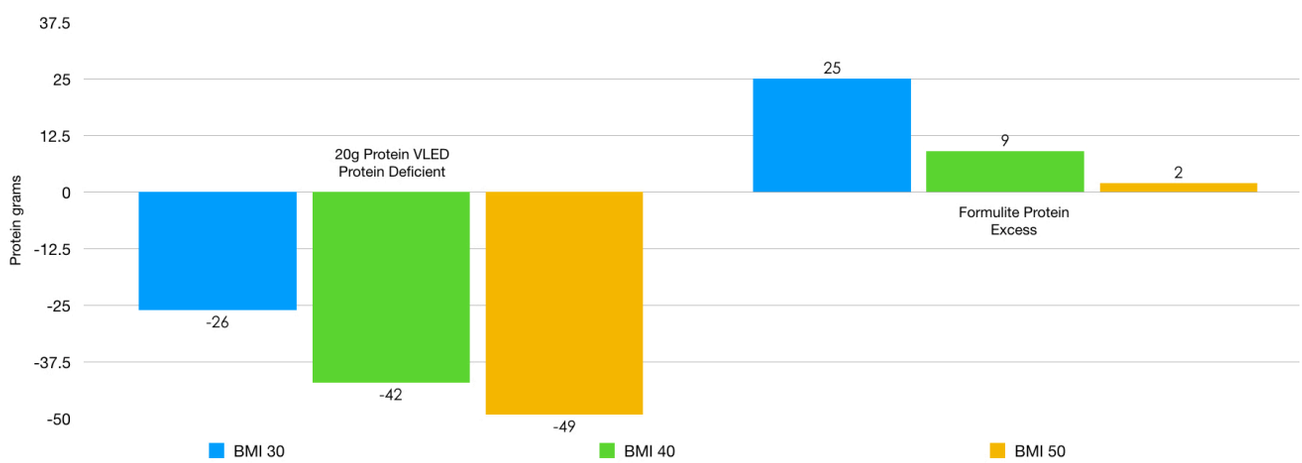
(DAA OSSANZ dietitian survey – based on Aug 2020 NIPs)

Product - 3 Daily	Energy KJ	Protein g	Carbohydrate g
Formulite	2673	105	31.8
20g Protein VLED	2520	60	54.6
Higher Protein VLED	2250	84	60

Most VLED products are prescribed as a 3-product program. As demonstrated in the graphs below, this standard 60g protein program falls vastly short of meeting actual dietary protein requirements.

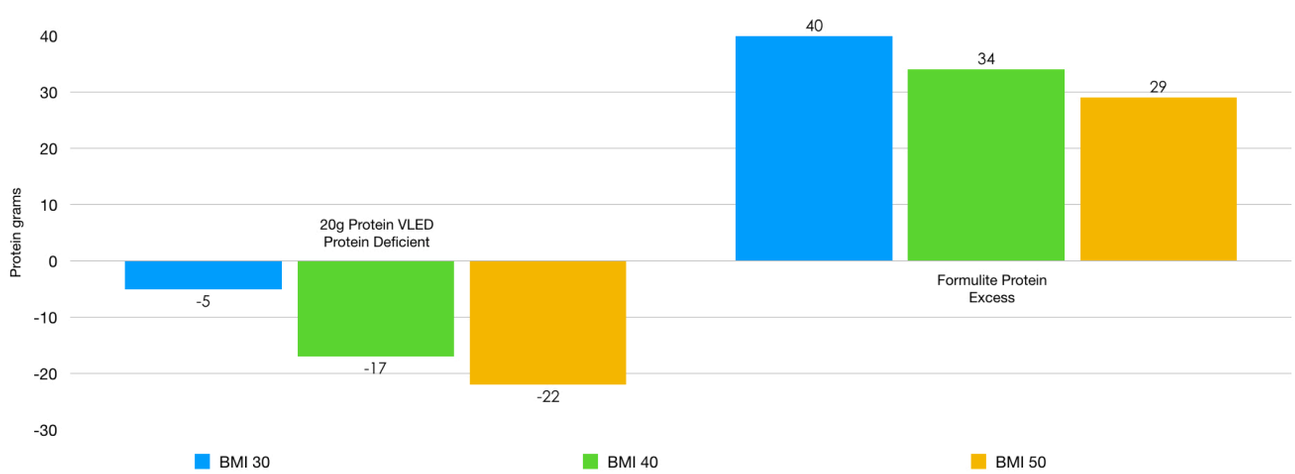
Protein deficit/excess VLED programs MEN

Gibson & Franklin et al (1)
3 daily VLED Protein RDI 0.94g/kg/day AIBW



Protein deficit/excess VLED programs WOMEN

Gibson & Franklin et al (1)
3 daily VLED Protein RDI 0.74g/kg/day AIBW



Simply adding another VLED product to provide extra protein is not ideal, as extra carbohydrate and energy will also be provided which may impact VLED effectiveness.

Formulite's high protein shake formulation with 33-34 g/serve meets the needs of all up to a BMI of 50 with a straightforward 3 shakes/day program.

The majority of obese patients using Formulite will not need extra products or extra protein serves to meet protein requirements.

There is strong evidence that higher protein diets >0.8 g/kg/IBW per day do attenuate loss of lean tissue mass (6,7,8).

The higher protein formulations also assist with satiety during the VLED than lower protein formulations (13). Please refer to Assessment of Protein (pg.7) for detail regarding calculation of protein.

Women = 80 - 100 g lean protein **Men** = 100 - 120 g lean protein

Program	Protein	Total Protein
3 Formulite Shake Plan	100 g	105 g
2 Formulite 100 g meat 1 dairy	68 g 25 g 9 g	102 g
2 Formulite 120 g meat 1 dairy 2 eggs	68 g 30 g 9 g 12 g	119 g

Note : Those with very high requirements may have 3 shakes/day + 1 meal which will provide an extra 35 g protein daily but only 10.6 g carbohydrate.

Refer to the Formulite VLED Meal Plan & Recipe eBook for menu suggestions and recipes.
Available on request from info@formulite.com.au.

Monitoring

It is recommended that patients are monitored by a healthcare professional during the Formulite program, particularly if they are at high risk with associated comorbidities.
Patients should be reviewed every 2-4 weeks. There is no data to support the recommended frequency of monitoring, but successful weight loss is more likely with closer supervision.

1. Monitor weight, waist circumference, blood pressure and pulse rate each visit

2. Monitor for adverse effects each visit

3. Review medications regularly
   - Diabetes medication (refer to next section)
   - Antihypertensives may need to be reduced as systolic and diastolic blood pressure decrease
   - Diuretics may need to be reduced or stopped as VLEDs cause fluid loss from glycogen depletion and ketonuria.
   - Warfarin and Lithium levels will need to be monitored more closely as metabolism may change.

4. Routine monitoring of blood tests is not usually required unless there is a concurrent medical condition that necessitates it such as diabetes, impaired renal function, diuretic use or gout

PRECAUTIONS WITH VLED

Unstable cardiac or cerebrovascular disease

- A VLED is not advisable for people that have suffered a recent myocardial infarction, stroke or unstable angina. Using Formulite to replace one or two meals per day may be suitable but should only be considered for those who are severely obese and used under the supervision of a medical practitioner.

Acute and chronic renal failure

- Patients with glomerular filtration rate (GFR) < 60 mL/ min require closer monitoring of electrolytes and renal function on a VLED. Those patients with GFR < 30 mL/ min should consult their nephrologist to determine suitability for the VLED.

Severe or end stage liver disease

- Weight loss is often recommended for obese patients with fatty liver disease, however rapid weight loss is not recommended for people with advanced liver disease. These patients may be more suitable for stage 2 or 3 of the Formulite program.

Psychiatric disorder and severe psychological disturbance

- A VLED is not recommended for people with a psychiatric disorder or psychological disturbances such as severe depression or bipolar disorder due to the potential side effects of extreme energy restriction and compliance issues. It should not be used in patients with alcohol or drug dependence.

Pregnancy and Breastfeeding

- Formulite is not suitable to meet the increased nutritional requirements of pregnant and breastfeeding women. The use of Formulite meal replacements should be postponed until after pregnancy and once breastfeeding has stopped.

Healthy body weight (BMI of 25kg/m2 or less)

- Formulite is not suitable for use as a VLED in people of a healthy body weight due excessive loss of lean body mass. Individuals with a BMI of 25kg/m2 or less may use Formulite meal replacements as a weight management tool, with the guidance and supervision of a dietitian.

Children, adolescents and the elderly

- Formulite as a VLCD is not suitable to meet the nutritional needs of children and adolescents under 18 years or elderly adults aged 65 years and over.

- It may be suitable to use Formulite as a partial meal replacement for these individuals at the discretion of a health care professional and under strict dietetic supervision.

Porphyria

- Formulite as a VLED is contraindicated in people with Polyphyria, as extreme calorie restriction can promote an attack.

Managing Diabetes During VLED

Patients with type 2 diabetes on medications will need to monitor blood sugar levels multiple times a day when starting the VLED. Insulin and sulfonylureas usually need to be reduced by 50%. Metformin, dipeptidyl peptidase 4 (DPP-4) inhibitors and glucagon like peptide 1 (GLP-1) agonists can be continued without dose change. GLP-1 agonists may aid weight loss by causing appetite suppression from reduced gastric motility. Sodium-glucose co-transporter 2 (SGLT-2) inhibitors should be ceased when starting a ketosis diet due to the increased risk of euglycaemic ketoacidosis (17).

Patients with type 1 diabetes can follow the VLED with more intensive monitoring of blood sugars and use of ketone strips to check ketone levels intermittently (ketone level >1.5mmol/l is indicative of an increased risk of diabetic ketoacidosis) particularly if blood sugars are high. Long acting, basal insulin should be continued but quick acting insulin may be reduced by approximately 50% depending on the degree of carbohydrate restriction and blood sugar levels.

Management of Side Effects

VLEDs have been used for many years in patients with multiple co morbid conditions and have no serious side effects (18).

Hunger

- In the first week hunger may increase then return to pre VLED levels.
- Ketosis induced in the VLED has been shown to reduce hunger compared to balanced low calorie diets (1200-1600kcal/day) (19)

Headaches and fatigue

- Headache and fatigue are usually transient and may resolve after 4-6 days
- Ketosis may lead to more stable blood sugar levels and improved energy levels

Constipation

- Consider addition of fibre supplement, increase water intake and exercise for constipation
- Incorporation of low starch vegetables will provide some fibre

Bad breath

- Halitosis may be associated with ketosis. Sugar free gum or mint may be helpful

Diarrhea

- Diarrhea can occur in patients who are lactose intolerant. Formulite has less lactose than other meal replacement formulations but if this is a problem lacteze tablets may be helpful

Dizziness related to hypotension

- Diuresis can occur secondary to ketonuria and glycogen depletion (20)
- Monitor blood pressure closely and reduce antihypertensives and diuretics. Maintain at least 2 litres of water intake per day

Hypoglycaemia

- Monitor blood sugars closely and reduce antidiabetic medications and insulin as described in previous section

Cholelithiasis

- The VLED may precipitate formation of gall stones. Adding 1 teaspoon of oil to the diet will help to maintain motility of the gall bladder

Gout

- Gout precipitation is rare. Monitor uric acid, which may increase temporarily in the first few weeks, and consider allopurinol if required (21)

Hyponatraemia, hypokalaemia

- Electrolyte disturbances is rare but patient on diuretic therapy or with renal impairment should be more closely monitored

Bone density

- Weight loss from any diet, not specifically VLED, causes reduction in bone density proportional to the amount of weight (22)

Beneficial Effects of Weight Loss

Studies have shown that even 5% weight loss can lead to medical benefits in obese patients (23).

Lipids

- Serum total cholesterol, LDL -cholesterol and triglycerides decrease. Serum HDL- cholesterol may decrease during the VLED but recovers after the VLED (24)

Glucose metabolism

- Insulin resistance in liver and muscles improves and blood glucose levels decrease
- Remission of diabetes has been shown in a number of studies post bariatric surgery but a recent study also demonstrated significant remission of diabetes following use of VLED in the primary care setting (25)

Blood pressure

- Systolic and diastolic blood pressure decrease

Hepatic steatosis

- Liver triglyceride content decreases. Alanine transaminase decreases

Other obesity related medical conditions that improve with weight loss include;

- Obstructive sleep apnoea
- Gastro oesophageal reflux
- Osteoarthritis

Long term maintenance

The commonly held belief that faster weight loss leads to faster weight gain has not been proven.

Maintaining weight loss is problematic regardless of a whether the diet is intensive or less intensive (26). Obesity needs to be approached as a long-term chronic condition as weight regain is common. The VLED can be used intermittently for weight maintenance particularly if the patient regains weight. Counselling regarding lifestyle and behavioral change and regular long term follow up is important for maintenance of weight loss.

BENEFITS OF FORMULITE

Highest protein VLED with 33-34 g/serve - this allows the high protein needs of most overweight patients to be easily met. Additional protein sources are not required (unless male and BMI > 50) if patients prefer a shake only program.

Low carbohydrate content 10.6 g/serve and only 3.1 g sugar/serve

A low carbohydrate VLED allows for the addition of extra food choices such as dairy, which assist nutrition as well as compliance, while not compromising liver shrinkage.

Gluten free and low lactose – average of 2.2 g per serve and contains no milk powder. Usually **well tolerated** by those sensitive to lactose.

Source of pre and probiotics - Lactobacillus acidophilus and Bifidobacterium lactis.

Source of natural digestive enzyme - bromelain aids with **digestibility and tolerance.**

Contains Dietary fibre - A soluble prebiotic dietary fibre which aids constipation management and assists **gut health.**

Whey protein concentrate, whey protein isolate and micellar casein – increases satiety and attenuates loss of muscle mass.

Contains Leucine - a vital amino acid involved in muscle synthesis and maintenance (6).

Source of Omega 3 fats - which assist in cardiovascular health and reduces inflammation.

Proudly made in Australia to suit Australian taste preferences

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FORMULITE

FORMULITE PRODUCT RANGE

Formulite shakes come in **5** delicious flavours

CHOC HAZELNUT • BANANA • CREAMY VANILLA • HONEYCOMB • COFFEE

Available in cost effective tubs, convenient single serve shake & takes and now available in sachets.

Formulite also offers a healthy range of lupin soups available in convenient sachets.

Disclaimer

The Formulite Clinical Protocol (FCP) is intended as a general guideline only for healthcare professionals. The FCP does not indicate an exclusive course of action or standard of care. When implementing the FCP, healthcare professionals must always take into account individual requirements and medical conditions and apply appropriate clinical judgment for each patient.

The FCP is not intended to replace the advice of a healthcare professional. If you are not a healthcare professional you should seek advice based on your individual needs from a doctor or dietitian before using Formulite.

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