OPTIFAST® VERY LOW CALORIE DIET

Fertility Protocol

Version 1

OPTIFAST VLCD is for the dietary management of obesity and must be used under the supervision of a healthcare professional.
Information for healthcare professional use only.

Nestlé HealthScience

OPTIFAST VLCD Fertility Protocol

The OPTIFAST VLCD Program aims to assist healthcare professionals to manage patients at medical risk, due to excess body fat. Overweight or obesity can create multiple fertility, pregnancy, inter and postpartum medical complications, which can put the patient, and their future children at increased risk.

While there is a comprehensive protocol for the OPTIFAST VLCD Program, it does not address its use in the dietary management of overweight and obesity in female and male infertility, pregnancy, inter and postpartum, endometriosis and polycystic ovarian syndrome patients. With this in mind, this protocol, specific to these circumstances has been developed in order to address any uncertainty that may be experienced by healthcare professionals utilising the OPTIFAST VLCD Program working with these cohorts of clients or patients.

The guidelines have been developed with input from a group of healthcare professionals with expertise in the field, consideration of direct patient experience and relevant available research. Due to the importance of nutrition in the role of reproduction, the guidelines provide a brief review of clinical evidence, along with patient suitability, adaptations to the program, and contraindications and precautions.

These guidelines are intended to be used alongside the existing protocols for the OPTIFAST VLCD Program, which are designed to support professional standards and best practice methodologies for the healthcare professional using them.

Fertility and pregnancy related circumstances significantly depend on modification of diet and lifestyle, which requires a multidisciplinary approach that is delivered best by a team of healthcare professionals.

Continuity of care is important from pre to post pregnancy. Contacting relevant healthcare professionals who are treating a specific individual can help all involved to work together as a co-ordinated team. It is recommended that patients seeking to lose weight with the OPTIFAST VLCD Program for reproductive health be supervised by a qualified medical practitioner.

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Please note:

Feedback or comments on how to further improve this protocol to make it more relevant to you and your practice will be acknowledged and appreciated.

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Contents

Fertility

Fertility is the ability to conceive and get pregnant. Conversely, infertility is defined as not being able to conceive within 12 months of actively trying (or 6 months for a woman over the age of thirty-five).

Review of Clinical Evidence

- Research[1] suggests that overweight and obesity amongst women of reproductive age may contribute to an increased risk of infertility and difficulty conceiving.
- Studies[1] suggest that insulin resistance, caused by overweight and obesity may contribute to anovulation or oligo-ovulation. Additionally, overweight and obesity may impair oocyte[2] maturation and receptivity of the endometrial lining for successful implantation. Being[3] overweight may also impair oocyte quality and by extension result in poorer quality embryos and increased risk of miscarriage.
- Studies[4] have shown that weight loss in women who are overweight or obese may improve fertility in those trying to conceive naturally, as well as those who are utilising Assisted Reproductive Treatment (ART)[5].
- One small prospective study[3] using meal replacements found that the women who completed the study had less oocytes collected at the time of in vitro fertilization after taking meal replacements than beforehand, so caution is advised[6] in using VLEDs immediately prior to egg collection until more research has been undertaken.
- Being[7] a healthy weight prior to conception reduces the risks associated with obesity during pregnancy.
- The OPTIFAST VLCD[8] Program has been shown to be an effective mechanism for weight loss, however, there are no studies investigating the role of OPTIFAST VLCD on fertility.
- Although there have been identified improvements in fertility through following a VLED, further research[4] is necessary to determine the significance and when VLEDs are best utilised.

Recommendations for Management

a) Patient Suitability

Women who are overweight or obese and are planning a pregnancy should aim to optimise their weight and metabolic health. A reduction in excess weight may help to improve the chances of conception.

OPTIFAST VLCD may assist women who are overweight or obese to optimise their weight prior to conception. Loss of weight may minimise risks of infertility by potentially reducing the adverse metabolic effects that excess body fat has on fertility status.

b) Adaptations to the OPTIFAST VLCD Program

Women who are overweight or obese have increased risks of neural tube defects[9]. It is recommended that women who are overweight or obese and are planning to conceive should consume 5mg (5000mcg) folic acid per day to reduce the risk of neural tube defects[10]. The Intensive Level of the OPTIFAST VLCD Program will provide 330–420mcg[11] of folic acid per day, depending on products chosen. Consequently, it is advised that women who are planning to conceive should take an additional folic acid supplement of at least 400mcg[12] per day to help meet their elevated recommended intake.

It is recommended that women planning to conceive take 150mcg–220mcg[13] iodine daily. The Intensive Level of the OPTIFAST VLCD Program will provide 210–290mcg iodine per day. As the Intensive Level of the OPTIFAST VLCD Program may not always meet recommendations for optimal conception, it is recommended that a supplement containing 150mcg[12] iodine be taken in conjunction with OPTIFAST VLCD daily by women who are planning to conceive.

Additional omega 3 fatty acids and vitamin D supplements may also be beneficial for patients on the OPTIFAST VLCD Program who are trying to conceive.

c) Contraindications and Precautions

Use of the Intensive Level of the OPTIFAST VLCD Program is contraindicated during pregnancy[8] as ketogenic diets may have an adverse impact on the growing fetus. Therefore use of the Intensive Level of the OPTIFAST VLCD Program should cease prior to conception.

Further research[8] is necessary to determine the effectiveness and most beneficial timing of the Intensive Level of the OPTIFAST VLCD Program for improving fertility in women who are overweight or obese, especially for women who are undertaking Assisted Reproductive Treatments (ART). Until further evidence is available, based on expert consensus it is recommended that clinicians consider ceasing the Intensive Level at least 6 weeks prior to egg collection, embryo transfers or actively trying to conceive. It is recommended that dietary and lifestyle supports are continued throughout the egg collection and embryo transfer to optimise ART results. 'Active 1' or 'Maintenance' levels of the OPTIFAST VLCD Program (with adequate nutritional supplements and supervision) may be considered.

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Male Fertility

Male factors are involved in up to 50% of cases of infertility. The health of a man impacts the health of his sperm.

Review of Clinical Evidence

- Research suggests that overweight and obesity is linked to infertility in men.
- Studies indicate that men with a BMI[1] greater than 25 are more likely to have a lower sperm count and quality[2].
- Obesity represents a modifiable risk factor for male fertility[3]. Although limited, the number of research trials into the impact of weight loss on fertility is gaining momentum.
- Research indicates that low calorie diets play a crucial role in improving the sperm quality of men who are overweight or obese[4].
- However, it should be noted that one study[5] of men who experienced severe weight loss with gastric bypass surgery found a correlation between weight loss and reproductive dysfunction, however this is believed to be related to the impact of nutrient restriction.
- Most studies[4] to date of male fertility have focused on micronutrients and not specific diets or caloric intakes. Diets rich in omega 3 fatty acids, antioxidants, vitamin D and folate have been associated[6] with increased fecundity in males. Diets high in saturated and trans fats have been linked to suboptimal semen quality.
- Research[7] suggests that high energy diets can lead to decreased sperm count and concentration. High energy diets have been associated[7] with an increase in testicular fatty acids and cholesterol, which may alter sperm plasma[8] and result in reduction in fertilisation rates.
- Evidence[4] from both human and animal studies indicate that male obesity and high-fat diets independently alter the physical structure of sperm. In contrast, low fat dietary intakes have been associated with higher sperm concentration and motility[4].
- To date, no weight loss interventions have been conducted with VLEDs to ascertain their impact on improving male fertility, with respect to achieving pregnancy.

Recommendations for Management

a) Patient Suitability

The OPTIFAST VLCD Program can assist with weight loss and may help increase fertility rates in males who are overweight or obese that experience fertility issues.

Ideally, men planning to optimise their fertility should achieve a healthy body weight well in advance of planned conception.

b) Adaptations to the OPTIFAST VLCD Program

It is recommended that individual requirements for key male fertility nutrients such as omega 3 fats, folate and vitamin D are calculated to ensure that the OPTIFAST VLCD Program meets these requirements. Additional supplementation may be required in some instances.

c) Contraindications and Precautions

It is imperative to note that no studies have been undertaken specifically to study the impact of the OPTIFAST VLCD Program on male fertility.

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Pregnancy

Pregnancy is the time when a fetus is developing in a woman's uterus.

Review of Clinical Evidence

- Current[1] statistics show that approximately half of all pregnant women are overweight when they conceive, which can lead[2] to a range of pregnancy complications.
- Rapid weight loss[2] during pregnancy is generally not recommended[3].
- Ketosis is generally not safe during pregnancy and should aim to be avoided. Animal studies[4] show mixed results as to the safety of ketosis during pregnancy. Possible complications include cognitive complications, physical deformities, nutritional deficiencies and behavioural issues in the offspring.
- Fluid loss caused by ketosis can lead to pregnancy complications such as constipation and urinary tract infections.
- Ketone bodies that are produced during ketosis cross the placenta, and may impact the growth and development[5] of the fetus.
- Excess carbohydrate restriction can contribute to a small weight gain/excess weight loss and increased risk of small for gestational age baby[6].

Recommendations for Management

a) Patient Suitability

Women who are planning to conceive or are pregnant should optimise their body weight and metabolic health well in advance of planned conception.

The Intensive Level of the OPTIFAST VLCD Program is not suitable for pregnant women due to the unknown risks associated with ketosis. Active 1 Level or Maintenance Level of the OPTIFAST VLCD Program may be able to be utilised for some women during pregnancy if closely supervised by their healthcare team to meet nutritional, carbohydrate and caloric requirements.

b) Adaptations to the OPTIFAST VLCD Program

OPTIFAST VLCD Shakes, Desserts, Bars and Soups may still be used as a single meal replacement throughout pregnancy as long as adequate nutritional status and foetal weight continues to be achieved.

It is important to note that requirements of micronutrients such as (but not limited to) folate, iron, choline and iodine increase during pregnancy. If Active 1 Level or Maintenance Level of the OPTIFAST VLCD Program are going to be used, it is essential that caloric, macronutrient and micronutrient requirements are calculated for the patient and supplemented as required. Regular micronutrient biochemistry testing and growth monitoring should be conducted regularly, at least every six weeks.

c) Contraindications and Precautions

The Intensive Level of the OPTIFAST VLCD Program is not suitable for women who are pregnant. This is due to the risk of elevated ketones in the blood, which may have negative impacts on the development of the fetus.

It also is not designed to meet the increased nutrient requirements needed during pregnancy.

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Postpartum

The postpartum period is the period following the birth of a baby where women may be breastfeeding and recovering from labour.

Review of Clinical Evidence

- Weight retained after pregnancy is defined as the difference between postpartum and pre-pregnancy weight. It is estimated that approximately 20%[1] of women retain at least 5kg one year postpartum.
- Postpartum weight retention is associated with[2] increased difficulties initiating and sustaining breastfeeding, and an increased risk[3] of chronic disease development.
- Breastfeeding is a time of increased nutritional[4] and caloric demand.
- Both fat (vitamins A, D, K) and water-soluble vitamins (vitamins C, B1, B6, B12, and folate) are secreted into breast milk and their levels are reduced in breast milk when there is a maternal vitamin deficiency[4].
- Diet and exercise[5] or diet alone appear to be safe for both breastfeeding and non-breastfeeding women and their infants. Exercise improves maternal cardiorespiratory fitness and preservation of fat free mass. The recommended weight loss is approximately 0.5kg/week[6].
- Ketogenic diets may induce[7] ketoacidosis during lactation due to dysregulation of glycogen stores. This forces the body to use gluconeogenesis as an energy substrate for breast milk production. This[8] restriction can alter maternal macronutrient metabolism, which could alter breast milk quality to impact infant development.
- Postpartum weight retention has been associated with an increased risk of postpartum depression[9]. Although no papers were found directly discussing the impact of VLEDs on postpartum depression, a meta-analysis found that when combined with behavioural therapy and low intensity exercise, a VLED of at least 8 weeks may benefit anxiety and depression in overweight or obese women[10].

Recommendations for Management

a) Patient Suitability

The OPTIFAST VLCD Program may be an effective postpartum weight loss strategy for women who have ceased breastfeeding, particularly if they are experiencing weight-related postpartum depression. The Intensive Level of the OPTIFAST VLCD Program is not recommended for mothers who are breastfeeding. Active 1 Level or Maintenance Level of the OPTIFAST VLCD Program may be able to be utilised for some women whilst breastfeeding if closely supervised by their healthcare team to meet nutritional, carbohydrate and caloric requirements.

b) Adaptations to the OPTIFAST VLCD Program

It is safe to use a single OPTIFAST VLCD product as a meal replacement during lactation, as long as ketosis is not induced, and all nutritional requirements are being met. In particular, it is recommended that energy, carbohydrate, protein, calcium, iron, folic acid, vitamin C, vitamin A and vitamin D intakes are calculated to ensure adequate consumption[11].

Mothers who have had a recent vaginal tear or delivery via Caesarean section may have increased protein and micronutrient requirements (particularly zinc and vitamin C) for wound healing.

For optimal results with postpartum depression, adjunctive behavioural therapy and low intensity exercise is recommended.

c) Contraindications and Precautions

Patients who have chosen to breastfeed are advised not to undergo the Intensive Level of the OPTIFAST VLCD Program, due to the effect it may have on milk production and quality.

It is imperative to note that no studies have been undertaken specifically to study the impact of the OPTIFAST VLCD Program on postpartum patients or their children.

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Interpartum

The interpartum period is the time between delivering a baby and conceiving the next.

Review of Clinical Evidence

- Weight gain is common[1] in the interpartum period.
- Pregnancy and breastfeeding can leave mothers with nutritional deficiencies[2].
- Even a modest gain of 1–2 BMI units (kg/m^2) between pregnancies may increase the risk[3] of gestational hypertension, pre-eclampsia[4], macrosomia, gestational diabetes, stillbirth[5] and Cesarean[6] section in subsequent pregnancies.
- Weight reduction between pregnancies is associated with[5] a decreased risk of large for gestational age infants in subsequent pregnancies but may result in an increased risk of small for gestational age (SGA) infants.
- Pre-pregnancy obesity is associated with higher rates of postnatal depression[7].
- The interpartum[8] period is an important time for optimising maternal body weight.

Recommendations for Management

a) Patient Suitability

In clinical practice, patients often return within 2–3 years to have their next child. On average they would breastfeed for 6 months to a year, try to conceive for 3–6 months and require 9 months of pregnancy. Hence there is often only a very short period of time in the interpartum period to optimise weight, making tools such as OPTIFAST VLCD (with adequate nutritional supplementation and close supervision) valuable.

b) Adaptations to the OPTIFAST VLCD Program

Due to an increased risk of nutritional deficiencies, women in the interpartum period planning to undertake the OPTIFAST VLCD Program may need to have at-risk nutrient levels tested and supplemented as required. These nutrients may include (but are not limited to) iron, iodine and vitamin D.

Women who are overweight or obese have increased risks of neural tube defects[9]. It is recommended that women who are overweight or obese and are planning to conceive should consume 5mg (5000mcg) folic acid per day up until 12 weeks of pregnancy to reduce the risk of neural tube defects[10]. The Intensive Level of the OPTIFAST VLCD Program will provide 330–420mcg of folic acid per day, depending on products chosen. Consequently, it is advised that women who are planning to conceive should take an additional folic acid supplement of at least 400mcg[11] per day to help meet their elevated recommended intake.

It is recommended that women planning to conceive take 150mcg–220mcg iodine daily[12]. The Intensive Level of the OPTIFAST VLCD Program provides approximately 210–290mcg iodine per day. As the Intensive Level may not always meet recommendations for optimal conception, it is recommended that a supplement containing 150mcg iodine[10] be taken in conjunction with OPTIFAST VLCD daily by women who are planning to conceive.

c) Contraindications and Precautions

The Intensive Level of the OPTIFAST VLCD Program should not be used whilst breastfeeding or in the weeks leading up to conception. Until further research is available, the expert consensus is to cease the Intensive Level at least six weeks prior to actively trying to conceive. 'Active 1' or 'Maintenance' levels of the OPTIFAST VLCD Program (with adequate nutritional supplements and supervision) may be considered.

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Serving suggestion

Endometriosis

Endometriosis is an inflammatory disorder where cells similar to those which line the uterus are found outside the uterine cavity.

Review of Clinical Evidence

- Research[1] suggests that overweight and obesity[2] has an inverse relationship with the incidence of endometriosis.
- Although an increased incidence of endometriosis is observed in women with low body mass indices, endometriosis is associated with conditions[3] common to obesity (hypercholesterolemia, hypertension and coronary heart disease).
- Studies[4] have shown that women with obesity were more likely to have moderate-severe endometriosis (stages 3–4) than mild (stage 1–2) endometriosis.
- Research suggests[5] a link between dietary intake and risk of developing endometriosis, as well as endometriosis symptom[6] severity.
- Endometriosis[7] is an inflammatory condition. Dietary intakes high in trans-unsaturated fats and refined carbohydrates have been linked to an exacerbation of endometriosis symptoms. VLEDs have been shown to help with inflammation in patients with heart disease, osteoarthritis[8] and psoriasis[9] so it could be extrapolated that there may also be a possibility that it is beneficial for endometriosis inflammation.
- Emerging evidence suggests that obese women with endometriosis have higher fertility rates[2] than women with lower BMIs[10].
- No studies have been conducted to date to investigate the impact of OPTIFAST VLCD in the management of endometriosis.

Recommendations for Management

a) Patient Suitability

Women who are overweight or obese with endometriosis may benefit from the OPTIFAST VLCD Program, however there is no significant evidence to suggest that weight loss will improve endometriosis symptoms and may actually worsen them.

Women requiring a hysterectomy to treat endometriosis may experience weight gain, and therefore may benefit from the OPTIFAST VLCD Program.

b) Adaptations to the OPTIFAST VLCD Program

Given caution is advised when losing weight with endometriosis, Active 2 or Active 1 Level of the OPTIFAST VLCD Program may be more suitable than the Intensive Level.

It is recommended that oils consumed with OPTIFAST VLCD be low in saturated fats to minimise inflammation.

A high intake of vegetables has been associated with an improvement in endometriosis symptoms. It is advised that women with endometriosis undertake a conscientious effort to meet their vegetable quota according to OPTIFAST VLCD guidelines.

Emerging research suggests there is a link between fermentable oligosaccharides, disaccharides, monosaccharides and polyols (FODMAPs) and endometriosis symptoms. OPTIFAST VLCD products contain a variety of FODMAPs so it is recommended that women with endometriosis wanting to use OPTIFAST VLCD do so under the guidance of an Accredited Practising Dietitian so that FODMAP intake (and consequently endometriosis symptoms) can be managed optimally.

c) Contraindications and Precautions

The lack of evidence for the use of VLEDs in reducing endometriosis risk should be noted and therefore only recommended in the case of women who are overweight or obese and trying to achieve a healthy weight. Caution should be taken and the patient's symptoms should be monitored by a healthcare professional if using the OPTIFAST VLCD Program.

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Polycystic Ovarian Syndrome (PCOS)

Polycystic Ovarian Syndrome is a hormonal condition associated with irregular menstrual cycles, high androgen hormones and polycystic ovaries.

Review of Clinical Evidence

- PCOS[1] is a complex condition characterised by insulin resistance hyperandrogenism, ovulatory dysfunction increased risks for endometrial hyperplasia, cardiovascular disease and diabetes.
- Research[2] shows that approximately 80% of women with PCOS are overweight or obese. Excess weight, particularly central obesity, may increase[1] insulin resistance and hyperandrogenism, exacerbating the clinical features of PCOS.
- It is recommended[3] that women who are overweight with PCOS aim to reduce weight by 5–10% in order to minimise symptoms and health complications associated with PCOS such as ovulatory dysfunction, oligo-ovulatory cycles and long term negative impact of endometrial hyperplasia and metabolic syndrome.
- PCOS[4] is associated with increased[5] fertility difficulties due largely to ovulatory dysfunction, poorer quality endometrial lining (affecting implantation) and increasing risks of miscarriage.
- Weight loss in women who are overweight with PCOS may assist[6] with insulin resistance and hormone regulation and a resumption in ovulation.
- A systematic review[7] outlined that there is not enough evidence to suggest an ideal weight-loss strategy for PCOS patients, however incomplete data does suggest that VLCDs may be an effective strategy. A VLCD program is considered[3] an effective alternative to standard low energy diets, especially in cases such as PCOS where achieving weight loss can be difficult.
- VLCD programs have been associated[3] with decreasing PCOS symptoms, including restoring hormone levels and ovulatory dysfunction. Restoration of ovulatory cycles is linked to enhanced fertility rates[6].
- Larger studies[2] need to be implemented to confirm whether VLCD programs are appropriate for women with PCOS, and their impact on ovulation and fertility.

Recommendations for Management

a) Patient Suitability

A VLCD program may be beneficial for women who are overweight or obese with PCOS to improve associated symptoms (including infertility), particularly if the patient has not achieved results with low calorie diets.

b) Adaptations to the OPTIFAST VLCD Program

Metformin is a medication commonly used in the treatment of PCOS. Metformin has been found to compromise vitamin B12 absorption, so women on the OPTIFAST VLCD Program who take metformin should routinely have vitamin B12 levels assessed and supplemented as required.

Emerging research suggests a link between PCOS and low vitamin D levels. Women with PCOS on the OPTIFAST VLCD Program should have vitamin D levels monitored periodically and supplemented as required.

PCOS has been associated with increased levels of systemic inflammation. It is recommended that oil consumed as part of the OPTIFAST VLCD Program is rich in unsaturated fats. Additional omega 3 supplementation may be considered by the treating practitioner.

c) Contraindications and Precautions

Women with PCOS may become fertile whilst on the OPTIFAST VLCD Program. Precautions should be taken regarding birth control if pregnancy is undesirable.

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Notes

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OPTIFAST VLCD is for the dietary management of obesity and must be used under the supervision of a healthcare professional.

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