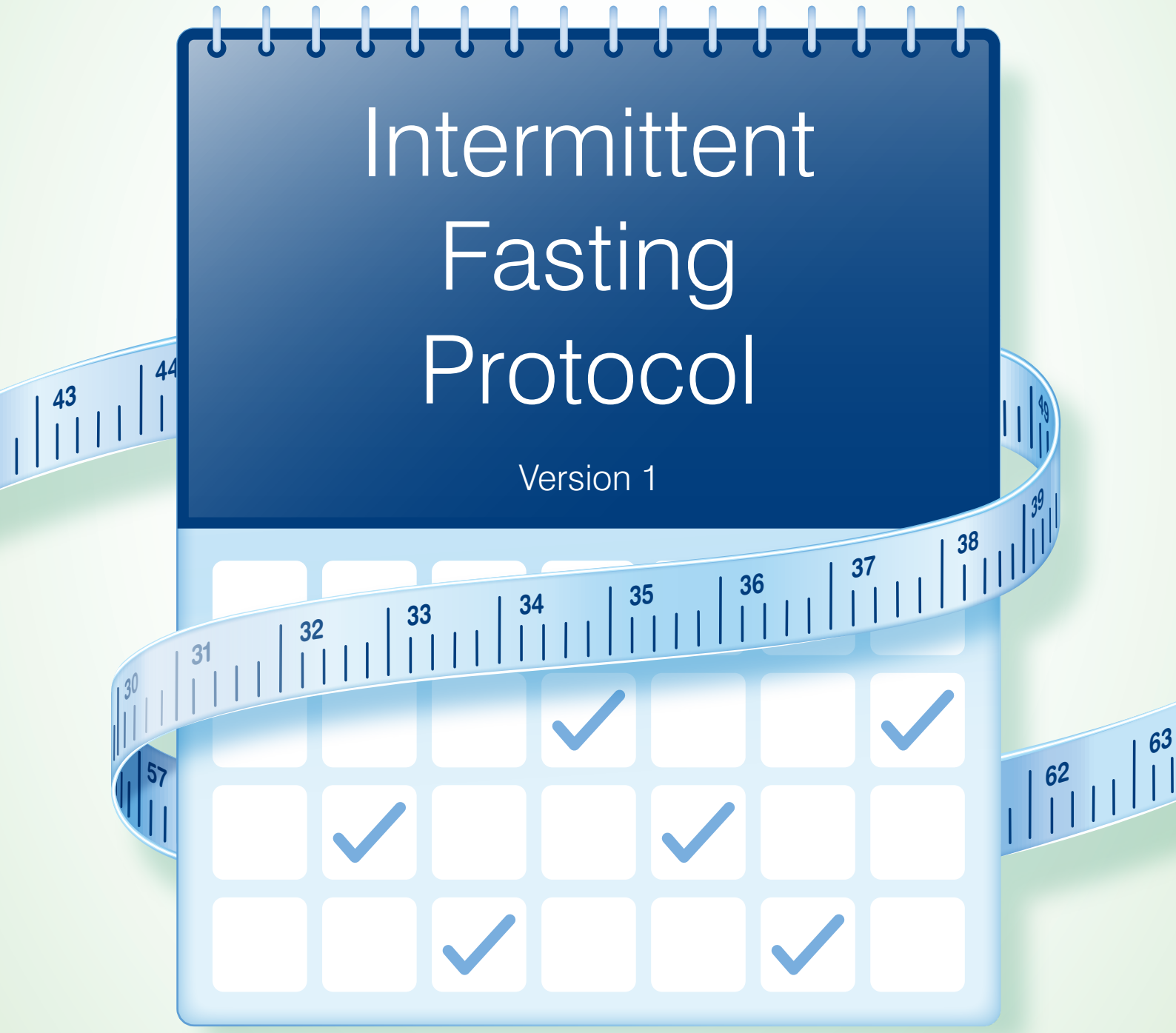
OPTIFAST® VERY LOW CALORIE DIET

Intermittent Fasting Protocol

Version 1



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


OPTIFAST
VERY
LOW
CALORIE
DIET

OPTIFAST VLCD Intermittent Fasting Protocol

The OPTIFAST VLCD Program aims to assist healthcare professionals to manage patients at medical risk, due to excess body fat. Overweight and obesity is associated with a number of chronic diseases and complications including type 2 diabetes, cardiovascular disease as well as many cancers.[1]

Studies have noted that weight loss of as little as 3–5% of initial body weight can induce clinically meaningful reductions in some cardiovascular risk factors, type 2 diabetes and osteoarthritis, with greater weight losses in individuals with overweight or obesity usually associated with greater health benefits.[2–5] Weight reduction and weight management strategies include lifestyle interventions (that is, changes in diet, physical activity and behaviour), pharmacological treatment[6] and surgery.[7,8] However, lifestyle interventions are the cornerstone solution for overweight and obesity in practice and is considered the first-line management option for overweight and obesity. Lifestyle interventions are also an important component of any pharmacological and surgical treatment.[5] One such lifestyle intervention for weight management is Intermittent Fasting.

These guidelines have been developed to provide guidance to healthcare professionals in the use of the OPTIFAST VLCD Program for Intermittent Fasting. 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.

Continuity of care is important, particularly where co-morbid conditions exist. Contacting other healthcare professionals who are treating a specific individual can help all involved to work together as a co-ordinated team. At all times the patient should be under the supervision of a qualified medical practitioner.

We would like to thank the following expert for their contribution, feedback and thorough review:

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Research Fellow

Please note:

We would appreciate any feedback or comments you may have on how to further improve the treatment guidelines and make them more relevant to you and your practice.

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Weight loss interventions

Continuous Energy Restriction and Intermittent Fasting

Lifestyle interventions to reduce or manage body weight usually incorporates advice on physical activity and continuous daily energy (caloric) restriction. Continuous energy restriction restricts energy intake or food intake to below weight maintenance requirements (usually around a 30% energy restriction from baseline energy requirements, ~2000 kJ/500 kcal per day) every day for an extended and often open-ended period of time. This strategy has been proven to be effective at achieving weight loss.[5,9] Although effective, it can often prove difficult for many individuals to stick to in the long term. Regardless of which diet one follows or the macronutrient content of the diet, adherence to continuous energy restriction typically declines over several months.[10] Due to the difficulty and effectiveness of these traditional or conventional continuous energy restriction approaches, for achieving and sustaining weight loss, there has been an increased interest in identifying alternative dietary weight loss strategies.

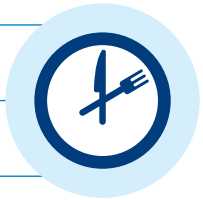
One such approach is intermittent fasting. While varying forms of intermittent fasting have been used for health and religious reasons for thousands of years, it has become increasingly popular as more and more individuals seek alternative ways to lose and manage their weight. Intermittent fasting is an umbrella term used to describe various dietary regimens that alternate between periods of *'fasting'* where energy intake is severely restricted, interchanged by periods of *'feeding'* where energy requirements are maintained. Given the less restrictive nature and 'break' from dieting every day, for some individuals, intermittent fasting has been found to be more acceptable, more appealing and easier to follow and maintain. The idea behind the intermittent fasting approach is that individuals do not fully compensate on their non-fasting days 'feed days' for the calorie deficit that occurs on their fasting days.[11–15]

Types of Intermittent Fasting diets

There are multiple versions of intermittent fasting, with fasting periods ranging from a number of hours to whole days of fasting – and commonly consists of a daily fast for 16 hours, alternate day fast for 24 hours, or a fast 2 days per week.

Time Restricted Feeding

Fasting Time	14–16 hours a day
Feeding Time	≤ 8–10 hours a day



Time restricted feeding involves fasting every day for 14–16 hours and restrict feeding to 8- to 10-hour windows or less each day.

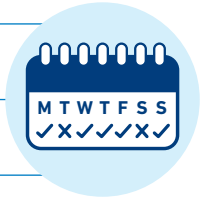
Alternate Day Fasting (ADF)

Fasting Time	Every second day
Feeding Time	Every other day

Alternate day fasting involves a 'feed day' where energy requirements are maintained, alternating with a 'fast day' where food is restricted to ~25% energy intake (i.e. 500 kcal – 600 kcal/day).

5:2 Style Diet[16]

Fasting Time	Any 2 days per week
Feeding Time	5 days per week



The 5:2 style of intermittent fasting involves five days of 'feeding' where regular eating patterns and energy requirements are maintained, interchanged with two days of 'fasting' (~25% energy intake [i.e. 500–600 kcal/day]) per week – these two days of fasting can be on consecutive or non-consecutive days. The 5:2 style diet elicits a weekly energy deficit of ~20–25%.

The most researched intermittent fasting diets are the alternate day fasting and the 5:2 style diet, with the 5:2 style diet being the most popular.[16] Here, the *OPTIFAST VLCD Intermittent Fasting Protocol* will focus on clinical evidence on the 5:2 style of intermittent fasting.

Review of clinical evidence

Research has shown that intermittent fasting is a credible and effective intervention for weight loss and health management. In many instances, intermittent fasting is comparable to continuous energy restriction for weight loss, however it may be a more manageable and a more sustainable option for some individuals.

Most studies that have evaluated the effects of a 5:2 style diet were designed as weight loss interventions, and many of these studies compare the 5:2 style dietary approach to continuous daily energy restriction (i.e. a diet based on around a 30% reduction of daily calorie intake from baseline energy requirements). The studies discussed below were conducted in adults with overweight and obesity.

Adherence to an Intermittent Fasting diet

Studies have shown that a 5:2 style diet has a similar adherence to continuous energy restricted diets.[17–20] However, two studies showed a greater dropout rate with the continuous energy restrictions as compared with the 5:2 style diet.[17,18] This may be because adherence is only needed on 2 days of the week rather than daily adherence. This suggests that a 5:2 style diet may be an appropriate alternative to the continuous energy restricted diet for individuals who tolerate it well.

Weight loss and body composition

Although individuals doing intermittent fasting only restrict their energy intake for a limited period of the week, evidence from systematic reviews demonstrate that intermittent fasting approaches, including the 5:2 style diet, achieve comparable weight loss and body composition outcomes to that of continuous energy restriction.[21–23]

Studies using 5:2 style dietary interventions have reported a weight loss of 5–8% during a period of 8–52 weeks.[17–20,24–26] Attaining at least 5% weight loss has been shown to improve some cardiovascular risk factors, type 2 diabetes and osteoarthritis[18,24] One study using a 5:2 style diet where fast days incorporated a commercially available total meal replacement diet (providing ~25% of their estimated energy requirements) showed weight loss of at least 5% within just 8 weeks.[24]

Additionally, a 5:2 style diet has been shown to be as effective as continuous energy restriction at not only inducing weight loss, but also producing beneficial effects on body composition[20,22,27,28] and may be more effective at reducing body fat and waist circumference.[17,18]

While weight loss can be achieved through a variety of different ways, long-term maintenance of weight loss is challenging. Similar to other diets, if a 5:2 style diet is ceased, weight regain may occur.[19,20,25] Therefore, weight maintenance strategies need to be implemented.

Energy intake/food intake

When looking at the evidence of energy intake/food intake in participants who have undergone a 5:2 style diet and continuous energy restriction, self-reported data from these studies show a lower energy intake during a 5:2 style diet compared to continuous energy restriction.[18,24–26] Previous studies have shown that participants following an intermittent diet do not overeat on the 'feed days' to compensate for the severe energy restriction on the 'fast days'. This is despite initial ratings of hunger reported in two studies to be higher during a 5:2 style diet compared to continuous energy restriction, although this appears to normalise over time.[19,26] However, another study reported no difference in hunger scores between a 5:2 style diet and continuous energy restriction diet.[17]

Diabetes

It is well-established that weight loss via energy restriction leads to improved metabolic outcomes, with a reduction of just 5% of body weight leading to improvements in glycaemic control.[27,29] For example, a 5:2 style diet and continuous energy restriction appears to have similar reductions in both fasting insulin and insulin resistance, although results were slightly superior following a 3- and 6-month 5:2 style diet compared with a continuous energy restriction.[17,18]

Intermittent fasting shows evidence of improving insulin sensitivity, therefore making it an attractive option for individuals with diabetes with overweight/obesity.[17,18,24,25] However, intermittent fasting strategies in patients with type 1 and type 2 diabetes could be challenging, as they may be associated with a need for modification in medication, an increase in blood glucose monitoring and an increased frequency of hypoglycemia.[28]

Cardiometabolic health

Although there are no clinical trials of the effects of intermittent fasting on major adverse cardiovascular events, a limited number of studies have assessed the impact of a 5:2 style diet and continuous energy restriction on cardiometabolic risk factors such as blood pressure, cholesterol and insulin changes. Studies have shown favourable improvements in cardiometabolic risk factors with a 5:2 style diet, such as a decrease in systolic and diastolic blood pressure[18,19,26] and decrease in total cholesterol, triglycerides and low-density lipoproteins (LDL) cholesterol, similar to that seen with a continuous energy restriction.[18–20,24,25]

In summary, the results in adults with overweight/obesity show that, following an intermittent or continuous energy restriction similar and favourable clinical outcomes are achieved. The 5:2 style diet is a form of intermittent fasting which provides a valuable intervention option for the management of overweight/obesity. Given the 'break' from dieting every day, some individuals may prefer a 5:2 style diet as they may find it easier to follow and maintain than continuous energy restriction.

Serving suggestion

Who is Intermittent Fasting suitable for?

Patient suitability

A 5:2 style diet has been shown to be safe and effective for adults 18 years and older, with overweight/obesity (≥25kg/m^2).[17–20,24] However, research on the benefits and safety of 5:2 style diets are limited for individuals under 18 years, as well as for older adults (over 65 years).

In addition, there may be potential contraindications and further investigation is needed on the effectiveness, practicability, and safety of intermittent fasting, in individuals with certain health conditions, such as type 2 diabetes, cardiovascular diseases, psychosocial barriers, pregnant and lactating women, young children, those who are older and frail and those with eating disorders.

Precautions

Type 1 diabetes

There is a lack of evidence for the use of intermittent fasting in individuals with type 1 diabetes. Although, a pilot study, in 10 individuals with type 1 diabetes and overweight/obesity, suggest that both the 5:2 style diet or continuous energy restriction are safe and effective weight loss approaches, more research in this area is required.[30] In order for patients with type 1 diabetes to safely adopt an intermittent fasting approach, it would be highly recommended that they monitor their blood glucose levels multiple times a day and have access to medical advice to enable medication adjustment.

Type 2 diabetes

Evidence for the safety and benefits of using intermittent fasting in patients with type 2 diabetes are limited in terms of randomised controlled trials. Studies that looked at the effects of a 5:2 style diet compared with continuous energy restriction on glycaemic control and weight loss in patients with type 2 diabetes reported that the change in weight, fat and fat free mass and reduction in HbA1c was similar between a 5:2 style diet and continuous energy restriction.[31]

Type 2 diabetes in patients not using medication

Intermittent energy restriction is safe for patients who have either diet-controlled type 2 diabetes or are using medication that is not likely to cause hypoglycaemia.

Type 2 diabetes in patients using medication

The most immediate risk with intermittent fasting is the potential for hypoglycemia in patients who are on medications, specifically insulin and sulfonylureas.[31–33] One study included individuals using sulfonylureas (n=18) and/or insulin (n=14), however the use of intermittent energy restriction required medication changes and regular monitoring, especially in the early stages. With the limited number of individuals on this study using insulin and sulfonylureas, more research in this area is required.

All other medication for diabetes when used either alone or in combination therapy (without insulin or sulfonylureas) are very rarely associated with hypoglycemia, and the risk is therefore considerably less, although still a consideration.

Therefore, intermittent energy restriction is acceptable for most patients with type 2 diabetes. Patients with diabetes who are interested in intermittent fasting should be encouraged to discuss the diet with their healthcare professional as it is important to assess their risks more carefully at the beginning of, and during the use, of a 5:2 style diet. Individuals who are not on glycaemic agents are not at risk of hypoglycaemia, and therefore suitable for intermittent fasting. For individuals using sulfonylureas and insulin, regular monitoring is important as it requires medication changes/adjustment on fasting days and regular glucose monitoring and fluid intake,[33] especially in the initial stages. It is important that individuals have regular contact with the appropriate healthcare professional to adjust medications as required. With proper medication adjustment and self-monitoring of blood glucose levels, intermittent fasting, specifically a 5:2 style diet can be encouraged and safely implemented among individuals with type 2 diabetes.

Adverse/side effects

Studies have reported only minor adverse effects with a 5:2 style diet, similar to that of very low energy diets.[17–19,25,26] These include:

- Feeling cold
- Tiredness
- Decreased energy levels
- Mild headaches
- Dizziness/light-headedness
- Constipation on energy-restricted days
- Lack of concentration
- Being preoccupied with food.

However, during a 6-month 5:2 style diet, a small number of participants reported less depression and increased positive mood and self-confidence.[18] This may have been due to the weight loss they were experiencing during the trial.

Refer to the *OPTIFAST VLCD Clinical Treatment Protocol* for tips on managing side effects such as these.

OPTIFAST VLCD as part of an Intermittent Fasting Protocol

OPTIFAST VLCD products can be integrated into an intermittent fasting protocol, by incorporating them into the two 'fast days', where the aim is to consume approximately 500–600 kcal/day.

During these 'fast days', individuals need to rely on a diet which is very low in calories to stay within the daily 500–600 kcal limit. This may be very challenging for many, as a very low-calorie, food-based diet means only a very small amount of calories can be consumed. The use of very low energy diet products on fast days can help individuals not only adhere to the very low energy requirement of 500–600 kcal/day, but also provides nutritionally complete meal options, thereby making it a safer and effective way to follow a 5:2 style diet.

How to use OPTIFAST VLCD products as part of Intermittent Fasting

If an individual is following the 5:2 style diet, consuming 3 x OPTIFAST VLCD Shakes on the 2 'fast days' will provide ~600 kcal and 60g protein. Different combinations of OPTIFAST VLCD products will vary the calorie intake, and therefore when the aim is to consume 500–600 kcal per day, calorie content of products will need to be considered. See Table 1 for OPTIFAST VLCD nutritional information.

For some individuals, including vegetables as per the Intensive Level of the OPTIFAST VLCD Program may aid in compliance, as well as providing extra nutrients. Although this will provide closer to 800 kcal/day, it will still incur an energy deficit on the 2 fast days. It is not essential to include the teaspoon of vegetable oil as 'fasting' is not occurring each day as it does when following the OPTIFAST VLCD Program Intensive Level.

If individuals find it hard to switch to 500–600 kcal/day, they can be advised to gradually, over a period of several months, reduce the food consumed during their fast days, with a goal of consuming 500–600 kcal/day:[34]

- 900–1000 kcal consumed 1 day/week for the first month
- 900–1000 kcal consumed 2 days/week for the second month
- 750 kcal consumed 2 days/week for the third month
- 500–600 kcal consumed 2 days/week for the fourth month (i.e. 3 x OPTIFAST VLCD shakes on each of the 2 fast days)

Drinking fluids and staying hydrated is a consideration for individuals of all ages who are participating in intermittent fasting, particularly on the fast days, in order to replace fluids that normally would be consumed in foods.

Physical activity is recommended for a number of health reasons and it important in terms of weight loss maintenance and preventing weight regain. Therefore, exercise is highly recommended on either fast or feed days when following any intermittent diet.

Table 1: OPTIFAST VLCD product information

Nutrition Information	OPTIFAST VLCD Shakes	OPTIFAST VLCD Protein Plus Shakes	OPTIFAST VLCD Desserts	OPTIFAST VLCD Soups	OPTIFAST VLCD Berry Crunch Flavour Bar	OPTIFAST VLCD Chocolate Bar	OPTIFAST VLCD Cappuccino Flavour Bar	OPTIFAST VLCD Cereal with Cranberry Bar
Serving size	**53g**	**63g**	**53g**	**53g**	**65g**	**70g**	**65g**	**65g**
Energy - Cal	201	250	201	201	227 kcal	233 kcal	230 kcal	210 kcal
- kJ	840	1050	840	840	950	980	970	880
Protein (g)	20	28	20	20	20.8	19.3	20.8	19.2
Carbohydrate (g)	18.2	20	18.2	18.2	19.5	23.4	20.8	22.1
Sugars (g)	9.5–10.1	2.2 1.9 (Choc)	8.5	10.1 8.5 (Veg)	7.5	7.1	7.5	5.2
Fat (g)	4.5	5.6	4.5	4.5	7.3	7.6	7.5	5.2
Fibre (g)	3.6	3.6	3.6	3.6	5.9	6.7	4.4	5.9

All nutritional values are averages.

Meal plans

Table 2: Sample meal plans using OPTIFAST VLCD products

	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday
~600 kcal Sample Meal Plan 1	Non-fasting Day	**Fasting Day** 3 x Shakes Calories: 603 Protein: 60g	Non-fasting Day	Non-fasting Day	**Fasting Day** 2 x Shakes 1 x Soup Calories: 603 Protein: 60g	Non-fasting Day	Non-fasting Day
~600 kcal Sample Meal Plan 2	**Fasting Day** 1 x Protein Plus Shake 1 x Bar 2 x cups low-starch veg Calories: ~600 Protein: ~50g	**Fasting Day** 1 x Shake 1 x Soup 1 x Dessert Calories: 603 Protein: 60g	Non-fasting Day	Non-fasting Day	Non-fasting Day	Non-fasting Day	Non-fasting Day
~750–800 kcal Sample Meal Plan 1	Non-fasting Day	Non-fasting Day	**Fasting Day** 3 x Shakes 2 x cups low-starch veg Calories: ~750 Protein: ~65g	Non-fasting Day	**Fasting Day** 1 x Shake 1 x Soup 1 x Dessert 2 x cups low-starch veg Calories: ~750 Protein: ~65g	Non-fasting Day	Non-fasting Day
~750–800 kcal Sample Meal Plan 2	Non-fasting Day	Non-fasting Day	Non-fasting Day	**Fasting Day** 3 x Protein Plus Shakes Calories: 750 Protein: 84g	Non-fasting Day	Non-fasting Day	**Fasting Day** 1 x Bar 1 x Shake 1 x Dessert 2 x cups low-starch veg Calories: ~780 Protein: ~65g

Monitoring / support

A healthcare professional should be consulted to ensure that the nutritional needs of the client / patient are being met and to provide continued counselling and education. As with all lifestyle interventions, it is important that healthcare professionals provide adequate information, ongoing communication and support, and regular positive reinforcement. This is particularly important when managing and maintaining weight loss. Studies have shown to reduce the extent of weight regain, while also maintaining reductions in fat mass and cardiometabolic risk factors, through continued engagement in weight loss maintenance programs lasting 4 to 26 weeks.[17,19,20,25] In studies that lacked continued counselling, weight regain occurred and cardiometabolic risks rebounded during follow-ups lasting approximately 6 months.[19,25]

There are no specific requirements for blood tests prior to undergoing an intermittent fast, however it is important for individuals to speak to the relevant healthcare professional about monitoring for specific medical conditions and medications.

As mentioned previously, patients with diet-controlled diabetes or those on medications that are not likely to cause hypoglycaemia, should discuss their interest in intermittent fasting with a healthcare professional. It is important that risks are assessed carefully at the beginning of a 5:2 style diet, and guidance and monitoring is provided throughout. For patients using sulfonylureas and/or insulin, intermittent energy restriction may require medication change, and regular monitoring of these patients is paramount.

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Notes

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