Cambridge Information for Doctors

Cambridge Diet Programmes

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This booklet summarises the weight care programmes available from Cambridge Health & Weight Plan and, in particular, the use of the Cambridge Diet as a Very Low Calorie Diet (or VLCD). The information given is intended to help doctors decide whether or not the Cambridge Diet programmes are suitable for individual patients and, if so, whether adjustment of medication dosage should be considered.

Introduction

The Cambridge Diet is a formula food VLCD that meets the nutritional needs of patients during weight loss. Extensively researched, such diet programmes are now established as a safe and effective method of weight loss, particularly useful in patients who have failed on conventional diet regimens. As such, the Cambridge Diet is an important management option for treating the increasing incidence of obesity in the UK.

A Department of Health report produced in 2006, Forecasting Obesity in 2010, indicated that over 24 million men and women (or 60% of the adult population) were overweight or obese in 2003 and predicted that these figures will rise to almost 28 million (66% adults) by 2010 (Ref 1). The National Service Framework (NSF) for Coronary Heart Disease (Ref 2) and the NSF for Diabetes (Ref 3) highlight tackling overweight and obesity as major preventive measures for which Primary Care Trusts and Health Authorities are required to develop protocols for implementation.

The Cambridge Diet is a flexible product. Cambridge Health & Weight Plan also provides a range of programmes using the Diet as a nutritional foundation with selected foods that range from under 600 kcal to 1500 kcal. Each programme has four stages: preparation, weight loss, stabilisation and maintenance. Anyone wishing to lose weight with Cambridge is advised to follow each stage as recommended to ensure long-term success.

Regulatory Framework

NICE Guidance on Obesity 2006

In December 2006 NICE published its guidance on Obesity with information for healthcare professionals, local authorities, schools and workplaces as well as patients, carers and the public at large. It acknowledged that the use of VLCDs is one option for the management of obesity. (Ref 26) It included guidelines of the use, duration and supervision of VLCD programmes. It recommended that patients should be supported in their choice of weight management options, wherever possible (Ref 27). The Cambridge programmes and protocols reflect its recommendations.

Another recent acknowledgement of VLCDs in general, and the Cambridge Diet in particular, as a viable and safe means by which some people might manage their weight is found on the NHS Choices website at http://www.nhs.uk/magazines/Obesity/Pages/ Keepweightoff.aspx

EU Legislation 1997

Total meal replacements above 800 kcal per day, and partial meal replacement programmes are subject to EU legislation - 'Foods Intended for Use in Energy Restricted Diets for Weight Control' (Ref 4) - implemented in the UK in 1997 as Statutory Instrument 2182.

VLCDs below 800 kcal per day will be subject to an extension to this Directive at some future date. The first step towards this is a data collection task of the EU's Scientific Cooperation Committee (SCOOP), published in 2002 (Ref 5).

The Cambridge Diet has always complied with current legislation and, in the interim period leading to EU legislation on VLCD, it complies fully with UK labelling and food safety legislation, as well as the COMA guidelines referred to below.

COMA Report 1987

The recommendations for using the Cambridge Diet as the 'sole source' of nutrition fully comply with the DHSS Report of the Committee on Medical Aspects of Food Policy (COMA Report) - 'The Use of Very Low Calorie Diets in the Treatment of Obesity' (Ref 6), except where they have been superseded by the NICE Guidance on Obesity referred to above.

The Role of the Cambridge Counsellor

Cambridge Health & Weight Plan believes that encouragement is just as important as dietary advice in helping a person to achieve a healthy target weight, and that it should continue into long-term weight maintenance. Cambridge weight management programmes are therefore only available to the general public through accredited Cambridge Counsellors. Selected Cambridge Counsellors are experienced in working in the Primary and Secondary Care environments and assist in the management of selected overweight and obese patients. These Counsellors are able to receive patient referrals from health professionals for those patients whose health is compromised and for whom a Cambridge programme is appropriate.

Composition of the Cambridge Diet

Nutritional Content

The Cambridge Diet can replace conventional food with a programme of drinks, soups, readymixed Tetra Brik drinks, and chocolate-coated meal bars providing a minimum daily intake of 415 kcal for women below 1.73m/5ft 8in or 554 kcal for all men and for women 1.73m/5ft 8in and above (see COMA 8.2.2).

Each drink or soup serving of Diet provides 138 kcal, giving 14.4g protein, 14.1g carbohydrate, 2.7g fat (of which saturates 0.4g), and 2.5g fibre, in addition to at least 33% of the Recommended Daily Allowance (RDA) given for vitamins, minerals and trace elements in Council Directive 90/496/EEC.

The meal bars are used to replace no more than one sachet per day. Each meal bar provides up to 172 kcal and has a different nutritional profile to the sachets, giving 10.7g protein, 24.7g carbohydrate, 5.8g fat (of which saturates 3.3g) and at least 33% of the EU RDA for vitamins, minerals and trace elements.

Nutrition Information

Typical contents of a Cambridge Diet sachet, when mixed with water, are shown in the table below.

			00ml when I with water	% of RDA	per 40 g serving	% of RDA	per 3 servings	% of RDA	per 4 servings
Energy	kJ kcal		219 52		584 138		1753 415		2338 553
Protein		g	5.5		14.6		43.7		58.2
Carbohydr	rate	g	5.3		14.2		42.5		56.6
of which Sugars		a	1.1		2.8		8.5		11.4
Polyols		g g	-		2.0		0.5		-
Starch		б g	4.2		11.3		34.0		45.3
Fat		ъ g	1.0		2.6		7.8		10.4
of which		0							
Saturates	5	g	0.2		0.5		1.4		1.9
Mono-ur	nsaturates		0.1		0.4		1.2		1.6
Polyunsa	turates	g	0.4		1.1		3.4		4.5
Choleste	rol	mg	0.9		2.4		7.2		9.6
Fibre		g	1.0		2.6		7.8		10.4
Sodium		g	0.2	10 5	0.5		1.4	400	1.9
Vitamin A		μg	100.0	12.5	266.7	33 33	800.0	100	1066.7
Vitamin D Vitamin E		μg	0.6 1.2	12.5 12.5	1.7 3.3	33 33	5.0 10.0	100 100	6.6 13.3
Vitamin C		mg mg	7.5	12.5	20.0	33	60.0	100	80.0
Thiamin		mg	0.2	12.5	0.5	33	1.4	100	1.9
Riboflavin		mg	0.2	12.5	0.5	33	1.6	100	2.1
Niacin		mg	2.2	12.5	6.0	33	18.0	100	24.0
Vitamin Be	5	mg	0.2	12.5	0.7	33	2.0	100	2.7
Folacin		μg	25.0	12.5	66.7	33	200.0	100	266.7
Vitamin B'	12	μg	0.2	25.0	0.7	67	2.0	200	2.7
Biotin		mg	_	12.5	0.1	33	0.2	100	0.2
Pantothen	ic acid	mg	0.7	12.5	2.0	33	6.0	100	8.0
Vitamin K		μg	15.0	*	40.0	*	120.0	*	160.0
Calcium		mg	113.9 125.8	14.2 15.7	304.0	38	912.0	114	1216.0
Phosphoru Iron	15	mg	125.8	12.5	336.0 4.7	43 33	1008.0 14.0	126 100	1344.0 18.6
Magnesiu	m	mg	37.5	12.5	4.7	33	300.0	100	400.0
Zinc		mg mg	1.9	12.5	5.0	33	15.0	100	20.0
Iodine		μg	18.7	12.5	50.0	33	150.0	100	200.0
Potassium		g g	0.3	*	0.8	*	2.5	*	3.4
Chloride		g	0.4	*	1.2	*	3.5	*	4.6
Copper		mg	0.4	*	1.0	*	3.0	*	4.0
Manganes	e	mg	0.5	*	1.3	*	3.9	*	5.2
Selenium		μg	15.0	*	40.0	*	120.0	*	160.0
Molybden		μg	30.0	*	80.0	*	240.0	*	320.0
Chromium	1	μg	15.0	*	40.0	*	120.0	*	160.0

Each serving also contains 1g linoleic acid and 0.13g of linolenic acid. The serving provides at least 33% of the Recommended Daily Allowance (RDA) given for vitamins and trace elements in Council Directive 90/496/EE

.* = No RDA given for this ingredient in Council Directive 90/496/EEC

Mechanism of Action

When used as the 'sole source' of nutrition, the carefully researched formulation of the Cambridge Diet allows a mild ketosis in most people. This has the beneficial effects of reducing hunger, improving alertness and promoting a sense of well-being, making it easier to adhere to the programme. The initial weight loss has a high water component associated with depletion of liver glycogen stores, which will be replaced during the re-feeding stabilisation stage of the programme.

If food is taken, even a small amount of carbohydrate, it stops the ketosis, encourages hunger, leads to water retention and reduces the rate of weight loss. (The higher carbohydrate level of the meal bars may impair the development of ketosis in some individuals.)

The best results are achieved with the least amount of discomfort if the Cambridge Diet is used as the sole source of nutrition by those for whom it is appropriate. The 'Sole Source' programme should not be used by those who only need to lose a small amount of weight, those who are BMI 25 or less (COMA 9.1.6), or those who are contraindicated.

Clinical Effects

The Cambridge Diet 'Sole Source' programme is a safe and effective way to achieve rapid weight loss - particularly for those needing to lose weight pre-operatively (Ref 7).

Weight losses of 1 to 2.5 kg per week in women or 1 to 3.5 kg per week in men, who were unable to lose weight with any other low calorie programme, have been achieved (Refs 8, 9).

In the first week there is a substantial fluid loss, but this lessens in subsequent weeks.

Fat loss is comparable to that achieved by starvation or gastroplasty (Ref 10) but without the harmful side-effects (Refs 11, 12).

Hunger is not a problem after about the first 72 hours once the mild ketosis develops and if the 'preparation' recommendations are followed.

Lean body mass proportion is maintained (Refs 11, 12, 13).

Electrolyte balance is maintained as well as with any effective diet (Ref 14).

Serum cholesterol is decreased by some 20 per cent (Ref 15).

Triglyceride is reduced by some 45 per cent (Refs 8, 13, 15).

No metabolic or clinical complications occur in Type 2 diabetes (Refs 9, 16, 17, 18).

No abnormalities are found in the ECG (Refs 8, 10, 19).

Hypertension is reduced (Refs 8, 10, 18, 20).

Resting metabolic rate T3 and T4 changes are equivalent to those on a standard 800 kcal diet (Ref 11).

Cambridge Diet Programmes

The 'Sole Source' programme

Three sachets daily of Cambridge Diet (four for women of 1.73m /5' 8" or above and all men) are made up with water as directed. An additional 2.25 litres (4 pints) minimum of water or other calorie-free fluid must be drunk each day - this may be in the form of water, black coffee or black tea. The water can be tap, still mineral water and a moderate amount of carbonated mineral water.

The following should **not** be taken whilst on the 'Sole Source' programme: sugar, any milk in tea or coffee; herb teas (except leaf herbs); flavoured carbonated drinks; low calorie squashes or slices of lemon in water or tea.

No other food should be taken (e.g. no snacks or vegetable nibbles).

The 'Sole Source Plus' programme

A slightly higher calorie programme (615 kcal/day) incorporating three or four sachets plus a small amount of milk or a small meal is available for those who may find the 'Sole Source' regimen too strict. This also includes the requirement to drink no less than 2.25 litres (4 pints) of water or other calorie-free liquid a day.

After the first week of dieting, exercise should be encouraged (Ref 25). Fitness with Cambridge has a complete range of exercise programmes for people with all different levels of fitness.

	St	tep 1	Step 2	Step 3	
Name of step	A: Sole Source	B: Sole Source Plus	810	1000	
Calories	415 - 554	615	810	1000	
What is eaten	3 - 4 CD*	3 CD* plus 200kcal meal OR 4 CD* plus 200ml of skimmed milk	3 CD* Add protein-rich foods, skimmed milk and some vegetables	2 CD* plus skimmed milk, breakfast, salads for lunch and dinner	
Typical duration once weight is lost for best results	1 week minimum, 12 weeks maximum		1 week minimum	2 weeks	
	Very Low Calorie Diet (VLCD)		Low Calorie	e Diet (LCD)	

Note on 'Sole Source' and 'Sole Source Plus' programmes

This 'Sole Source' and 'Sole Source Plus' programmes should not be undertaken (individually or in combination) for more than twelve weeks at a time, unless under medical supervision (NICE Guidance, 2006). They can then be resumed, if necessary, after at least one week on a higher calorie (800 kcal+) programme.

Other Cambridge Weight Management Programmes

The Cambridge Diet makes the ideal nutritional foundation for any diet. It is impossible to achieve complete nutrition from conventional foods on less than 1500kcal, but Cambridge weight care programmes under 1500kcal meet all known nutritional needs. There are several programmes at different calorific levels to suit individual needs.

	Step 4	Step 5	Step 6	N ne yc Sc ar		
	1200	1500	Maintenance	or wi		
	1200	1500	1500+	A ar		
F	2 CD* plus skimmed milk, breakfast, lunch and dinner	1 CD* plus skimmed milk, breakfast, lunch, dinner and snack	A healthy diet plus your choice of using CD*	nc *(
	2 weeks	2 weeks	Indefinitely			
	Not Low Calorie Diet (NLCD)					

Notes: Your doctor will need to be informed before you can start on 'Sole Source', regardless of BMI, and clinical supervision is optional if the doctor wants.

All Cambridge programmes are subject to the client not being contraindicated. *CD = Cambridge Diet

Medical Precautions

As with any weight loss programme, it is recommended that patients should consult their doctor before commencing any Cambridge Diet weight loss programme. It is accepted that the use of the 'Sole Source' programme as currently directed is safe for those in good health (COMA 5.1.4). However, in order to comply with the NICE Guidance which recommends that VLCDs below 600 kcal/day should be closely monitored, the Cambridge Counsellor will notify a doctor whose patient has opted to undertake such a programme (and for whom no contraindications exist). This allows the doctor to monitor their patient.

Any form of severe dieting may be undesirable in those with certain medical conditions or receiving certain medications. Such people should only follow any weight reducing diet with the express authorisation of their practitioner. This has always been the policy of Cambridge Health & Weight Plan and was endorsed by the COMA Report (COMA 9.1.3).

Contraindications

Dieting using the Cambridge Diet is contraindicated in:

- Pregnant and lactating women
- Children below the age of 14
- Coronary thrombosis or myocardial infarction within the last three months
- Cerebro-vascular accident within the last three months
- Unstable ventricular arrhythmias (even when apparently stabilised on treatment)
- Major surgery or trauma within the last three months (where a positive protein balance is necessary)

- Impaired renal or hepatic function
- Severe depression
- Use of MAOIs as anti-depressants
- Anorexia nervosa or bulimia nervosa
- Porphyria
- Milk protein allergy (the Diet is milk based)*
- Severe lactose intolerance (the Diet is milk based)*

*A range of soy-based drinks and soups are available for those who cannot tolerate cows' milk.

Adolescents

Children below 14 who need to lose weight should be under the supervision of their doctor and should not use any Cambridge programme.

Those between the ages of 14 and 18 are first encouraged to follow advice given in the 'Balance of Good Health' and to increase levels of activity. If this is unsuccessful, then a Cambridge programme with food (1000 - 1500 kcal) could be followed but the involvement of the child's parent or guardian and doctor should be encouraged wherever possible.

If a Sole Source or 810 kcal programme is specifically requested by those between 14-18, then parental involvement is necessary, and the doctor must be consulted and kept informed of progress.

Over 70s

The Cambridge Diet 'Sole Source' programme is not contraindicated to those over 70 if they are in good health. Caution is required in use with patients suffering from postural hypotension. It is recommended to seek the doctor's advice before commencing the Diet.

The Cambridge Diet used with Certain Medical Conditions

Diabetes

Patients with Type 1 and Type 2 diabetes may use the Cambridge programmes, dependent on close monitoring by their doctor, diabetes nurse, and Cambridge Counsellor.

If the patient is using Metformin, then any programme may be used, in conjunction with the Cambridge diabetes protocols.

Insulin-dependent diabetes patients and those on any other medication for diabetes may use any programme except 'Sole Source' and 'Sole Source Plus', dependent on adherence to the Cambridge diabetes protocols.

Other conditions

The Cambridge Diet 'Sole Source' and 'Sole Source Plus' programmes are suitable for patients with the following disorders, subject to agreement of and supervision by the medical practitioner:

Disorder	Use of Diet	Action
Angina	Weight loss will be beneficial for overweight patients	Adjustment or reduction of medi- cation may be necessary
Cardio-vascular disease	Not contraindicated if patient is in a stable condition. Weight loss will be beneficial for overweight patients; cholesterol and coagulation factors are diminished	Adjustment or reduction of medi- cation may be necessary
Cardio-vascular or cere- bro-vascular accident more than three months ago	Not contraindicated if patient is in a stable condition	'Sole Source' dieting should be under medical supervision
Diabetes	See above	See above
Gout	All VLCDs produce a rise in serum uric acid levels which may precipi- tate an attack during early stages of dieting	For known sufferers, prophylaxis with Allopurinol is recommended whilst using 'Sole Source'
Renal disease	Although contraindicated in severe renal disease, the Diet may be used 'Sole Source' with caution in less severe cases	The dietary content should be taken into account when deciding on medical management - three daily servings of Diet will provide 1.5g sodium, 2.5g potassium, 43.2g protein; four servings will provide 2.0g sodium, 3.4g potassium, 57.6g protein
Rebound hypoglycaemia	Not contraindicated as this condition is rarely prolonged	A high fluid intake normally reduces the symptoms
Depression	Not contraindicated except in severe depression; weight loss could have beneficial psychological effects for overweight patients	Doctor to advise; lithium must be monitored and dosage may need to be adjusted

The Effect of the Cambridge Diet on Certain Medications

Like all VLCDs, the Cambridge Diet 'Sole Source' (and 'Sole Source Plus') programme and the subsequent weight loss modify some conditions which means that medication may have to be discontinued, dosage changed, or the Diet used with caution.

Medication	Use of Diet	Action
Diuretics	The osmolar diuresis resulting from low carbohydrate content of the Diet – when combined with that of the medication – could give rise to excessive potassium loss and hypotension	Diuretic medication may need to be reduced and potassium supplementation given. Monitoring of potassium levels advised
Antihypertensives	Blood pressure falls with weight loss in 85% of patients	Medication may need to be reduced or discontinued when either 'Sole Source' programme is started
Oral hypoglycaemics	Blood sugar levels fall early in dieting due to reduced carbohydrate and calorie intake	Medication may need to be reduced or discontinued when either 'Sole Source' programme is started
Oral anticoagulants	The reduced calorie intake will potentiate drug absorption	The 1200 kcal programme is recommended
Anti-arrhythmia	The reduced calorie intake will potentiate drug absorption	The 1200 kcal programme is recommended
Anticonvulsants	The reduced calorie intake will potentiate drug absorption	The 1200 kcal programme is recommended
Lithium	The reduced calorie intake will potentiate drug absorption	The 1200 kcal programme is recommended
Steroids	Lower rates of weight loss may be experienced in some cases	

Potential Side Effects

Some possible causes and short-term remedies

During the first few days on the Cambridge Diet 'Sole Source' programme a small proportion of patients may experience transient side effects, such as those commonly found with many other weight loss regimens. These include headaches, mild dizziness, constipation, diarrhoea, nausea, irritability and dryness of skin. For most people the advantage of losing weight overrides any such short term discomfort which may be experienced.

Adherence to the 'Preparation' recommendations for the first week of the programme will minimise the possibility of most side effects. The importance of adequate fluid intake throughout the weight loss process cannot be stressed enough in increasing comfort levels and reducing the risk of these minor side effects. Fluid intake should be equivalent to at least 2.25 litres each day.

Headaches may occur due to dehydration or, more rarely, because of carbohydrate or caffeine withdrawal. In most cases an increased fluid intake reduces the problem. If this is not adequate, a simple analgesic taken for a day or two should alleviate the problem.

Constipation - bowel movements are less frequent because the Diet contains only a small amount of bulk. A high fluid intake reduces the problem. If the patient has a tendency to constipation, a natural bulking agent without added calories such as Fibre 89 (exclusive to Cambridge Health & Weight Plan), Fybogel or Isogel can be used.

Nausea and diarrhoea may occur as a result of the concentration of minerals and vitamins in the Diet. Drinking plenty of fluid before each serving of Cambridge Diet or taking half a portion six (or eight) times a day should alleviate the symptoms. Some patients with persistent diarrhoea may have previously unsuspected lactose intolerance.

Temporary hair loss is rare and is only seen in those patients who have an excessive amount of weight to lose over an extended period of time. "Significant hair loss occurs in about 10% of patients using VLCD for a longer period. Hair loss is diffuse and not complete. It may cause cosmetic problems and patients find it annoying but otherwise it is harmless and temporary. Hair starts to grow again after a few months" (Ref 18).

Weight Maintenance

Long-term Weight Maintenance:

Long-term assessment of VLCD with active follow-up treatment, behaviour modification and support seem to be one of the better treatment modalities related to long term maintenance success (Ref 21, 22, 23, 24).

Conventional Foods

Stabilisation and long term weight maintenance are the most important parts of any weight loss programme.

Following the 'Sole Source' programme, conventional foods are reintroduced in a specific and structured way. Energy intake is gradually increased (see the Diet Steps diagram on page 8). Patience at this stage is important and the total stabilisation period should not take less than eight weeks.

The maintenance process starts when energy intake has increased to 1500 kcal per day. Encouragement from the Cambridge Counsellor is available every step of the way to promote the necessary lifestyle changes to prevent weight regain. Advice on improved dietary habits to maintain the new lower weight is essential. Healthy eating guidelines, menu suggestions and recipes are available in the form of the 'Weight Care with Cambridge' booklet supplied by the Counsellor.

Cambridge Diet can also be used as part of daily energy intake to keep the total calorie intake under control.

If weight gain occurs, energy intake should be reduced to an appropriate level. (See the Diet Steps diagram on page 8.)

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 "Full Guideline section 1 Introduction, methods and recommendations", page 119.
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 Booklet "Information for people who use NHS services - Treatment for people who are overweight and obese", page 3.

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