Study aim
A pilot study was carried out to examine the effect of a VLCD programme on a group of obese (BMI ≥ 30) patients with diabetes. These patients remained obese despite enormous efforts by the multidisciplinary team (including primary care). Usually, there was also poor glycaemic control.

Method
Between January and June 1999, 24 patients aged 29–76 years were enrolled into Lipotrim (Howard Foundation Research, Cambridge, England), a VLCD programme which gives 450 kcal per day for women and 600 kcal per day for men. For entry to the programme, each patient had to:

- Understand the programme
- Desire to take part
- Undertake to attend weekly individual and group sessions
- Have family support
- Be desperate or determined to lose weight.

The product was available from the hospital at a cost of £18 per week for women and £24 per week for men. The expenditure for each patient was offset against money saved by not purchasing normal food.

The treatment of the obese individual with poorly controlled diabetes is a common and perplexing problem. Wading in with ever increasing amounts of insulin without giving thought to ameliorating the inevitable weight gain will cause desperation in the multidisciplinary team and despondency in the patient. Very low calorie diets (VLCDs), of <800 kcal per day, are designed to achieve substantial weight loss while preserving lean body mass and are typically associated with a 20 kg weight reduction in three months (NTFPTO, 1993). Unfortunately, regain of half to two-thirds of the initial weight loss is common within 12 months after cessation of the diet, although there may be longer term benefits in terms of a reduction in the need for medication in obese individuals with diabetes (Wing et al, 1994).

Recently, Paisey et al (1998) compared VLCD with a traditional intensive dietary regimen in 30 obese (BMI > 30) patients with diabetes and 19 obese controls without diabetes. After four months of VLCD, subjects were switched to a low-fat diet and continued to be seen weekly by the multidisciplinary team. Weight loss was substantial and maintained after cessation of VLCD (mean 14 kg at 12 months), and 14 of the 15 patients who had chosen VLCD had normal blood glucose and fructosamine levels despite stopping all medication. For four patients with recent-onset diabetes, normalisation of blood glucose levels was sustained for 12 months.

Lipid-lowering medication was stopped on entry to the programme. Weight, blood pressure and urinary ketones were measured once weekly up to refeeding then weight
and blood pressure were measured at every patient contact thereafter. Lipid levels and HbA1c were measured at the start of the programme, every month for the first six months then at three-monthly intervals for the next six months.

Patients were expected to attend the individual and group sessions at each visit (every week). In the individual sessions with the nurse, patients could discuss any problems they had encountered (Figure 1). Group sessions provided support, an opportunity to exchange experiences and preparation for refeeding. The dietitian was involved around the time of refeeding, to reinforce product literature from the company.

Most patients refeed at 3–4 months, and then followed a low fat healthy eating plan. After refeeding, follow up continued weekly for the first month, then every 2–4 weeks (frequency at the patient’s discretion). However, group sessions stopped at six months into the programme.

**Results**

Average body mass index (BMI) was 39.5 at the start of the study. Of the 24 patients:
- 16 were being treated with insulin
- 14 were hypertensive and were receiving appropriate medication
- 14 had dyslipidaemia and were receiving appropriate medication
- 2 were suffering from sleep apnoea requiring continuous positive airways pressure.

Following the introduction of VLCD, there were significant reductions in body weight (Figure 2) and BMI (Figure 3).

Data on HbA1c levels, plasma lipids, blood pressure and insulin requirements of programme participants are shown in Table 1. Plasma lipid levels remained largely unchanged. Only four patients restarted lipid-lowering medication after refeeding.

Blood pressures dropped significantly within the first week, and adjustment of antihypertensive medication was necessary on a regular basis. Eleven patients stopped all antihypertensive medication.

For most patients, ketone levels were moderate to high during the VLCD (indicating adherence to the programme and utilisation of fat stores).

Insulin doses were decreased by two thirds on commencement of the programme, and this seemed to work well, with insulin doses continuing to decrease as weight loss proceeded. Most patients who remained on insulin were changed to nocte insulin.
when their requirements were less than 14 units a day. Sulphonylureas were also halved or stopped on commencement of the programme.

Only 13 patients completed follow up for the 12 months of the programme. The three case histories (see page 111) provide further detail about some of the patients in the programme.

Discussion

Benefits of VLCD

VLCDs can be an effective method of reducing weight, improving glycaemic control — at least in the short term — and reducing the need for concomitant medication in obese people with diabetes. They can also allow individuals to gain insights into the potential benefit of weight reduction and to learn about the relationship between food and obesity.

When asked why this diet had worked while all others had failed, our patients said that it was easier to have no food at all, than to try to make choices from food offered, particularly on social occasions. Also the rapid weight loss experienced on the programme was positive reinforcement, together with the feeling of ‘wellbeing’ experienced as a consequence of ketosis (Burley et al, 1992).

Some considerations

It is well known, however, that helping someone to maintain weight loss is often the most difficult and disappointing task (Wing, 1995). In addition, the process is very time consuming for any healthcare professional involved. This pilot project to examine the effectiveness of VLCDs involved seeing 24 patients every week for 3–4 months, then at least monthly for the following nine months. We have only touched the ‘tip of the iceberg’ in our clinic population. If this service were offered to all of our obese patients (at least 60% of the total), a 50% uptake would involve 2250 patients who would require 11 whole time equivalent healthcare professionals just to provide weekly visits! In practice, this would be unrealistic and unlikely to attract funding, though one could argue that treating the root cause of the problem is far better than attempting to treat the effects.

Putting VLCD into practice

In many areas, primary care is offering Lipotrim to its obese patients. If the expertise of practice nurses and community dietitians in using this product could be built up, and the diabetes team was available for advice on medication changes for people with

| Table 1. HbA1c and lipid levels, blood pressure measurements and insulin requirements of participants during the course of the VLCD programme (mean±standard error) |
|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|
| Time            | 0 months n=24   | 3 months n=24   | 6 months n=20   | 9 months n=22   | 12 months n=13  |
| HbA1c           | 10.0±0.36       | 9.2±0.4 P≤0.05  | 9.0±0.5 P≤0.05  | 9.9±0.5 ns      | 10.0±0.5 ns     |
| Cholesterol     | 5.5±0.2         | 6.1±0.3         | 6.1±0.3         | 5.8±0.2         | 5.8±0.3         |
| HDL             | 1.1±0.05        | 1.0±0.04        | 1.03±0.04       | 1.02±0.03       | 1.03±0.03       |
| Triglycerides   | 2.7±0.3         | 2.5±0.4         | 2.8±0.3         | 3.1±0.4         | 3.4±0.5         |
| Blood pressure  | 159/86 ±4.3/1.7 | 137/81 ±4.3/1.8 | 138/82 ±4.4/1.2 | 145/85 ±4.0/2.4 | 143/83 ±3.6/2.1 |
| Insulin         | 44±8.3 P<0.001  | 11±3.3 P<0.001  | 15±4.7 P<0.001  | 19±5.3 P<0.001  | 28±7.8 P<0.01   |

ns=not significant (P>0.05); HDL=high density lipoprotein.
VLCDs can also reduce the need for type 1 diabetes under close supervision (as well as carefully selected people with control in obese people with type 2 diabetes reducing weight and improving glycaemic control). This study advocates the use of VLCDs for patients with type 1 diabetes, we feel that they should only be offered the programme under the supervision of an experienced diabetes team, and then only if the patient is able to self-adjust insulin appropriately and understands the risks.

**Conclusion**

This study advocates the use of VLCDs for reducing weight and improving glycaemic control in obese people with type 2 diabetes (as well as carefully selected people with type 1 diabetes under close supervision). VLCDs can also reduce the need for concomitant medication. While on a VLCD, individuals can become empowered through their increased awareness and knowledge of their diabetes and the positive feedback provided by the rapid weight loss.

It is likely that lack of time would limit the widespread adoption of the VLCD service used in this pilot study. However, the potential benefits of VLCD make it worthwhile to try to produce a cost-effective service, perhaps by increased primary care involvement.

**Case history 1**

**Mrs ED, age 71, type 2 diabetes diagnosed in 1982, converted to insulin in 1994. Also has hypertension, dyslipidaemia, coronary artery disease and osteoarthritis of the hips.** Was taking 42 units of insulin daily and metformin 500 mgs tds. Started the programme in May 1999. Her weight reduced from 86.9 to 62.6 kg (a difference of 24.3 kg), her BMI reduced from 34.8 to 25, and her blood pressure reduced from 177/89 to 154/77, despite stopping bendrofluazide and ramipril. Her HbA1c has improved from 9.9% to 7.7% (normal range <6.5%) despite stopping insulin, but Amaryl 2 mg was introduced after 6 months on the programme.

She tells us her weight loss has made her feel more confident—it is now a delight for her to shop for clothes instead of a penance. Physically she is brighter with more energy, her angina has improved so she no longer has to sleep in a chair, and she says she can now bend down to do things and has no pain from her arthritis.

**Case history 2**

**Mr MT, age 40. Had impaired glucose tolerance with hypertension and dyslipidaemia.** Started the programme in June 1999. His weight reduced from 159.8 to 98.8 kg (61 kg difference), his BMI reduced from 45.5 to 28, and his blood pressure reduced from 183/102 to 137/75, despite stopping propranolol, lacidipine, frusemide and halving his dose of lisinopril. His HbA1c has improved from 6.7% to 5.9% (normal range <6.5%), and he now has normal glucose tolerance.

He tells us he now feels much more confident, generally brighter and that people keep telling him that they don’t recognise him. He has been overweight since childhood, was teased at school and found it difficult to make friends.

**Case history 3**

**Mrs KG, age 30. Type 1 diabetes since 1978 (age 11).** Started the programme in March 1999. Her weight reduced from 79.4 to 64.6 kg (14.8kg difference), her BMI reduced from 30 to 25, and she has maintained her current weight for 9 months since refeeding.

She says she now feels more confident, needs less insulin and has gained a greater understanding of the relationship between carbohydrate and insulin.

**Special considerations:** As she has type 1 diabetes, she still needed regular insulin during the day with her formula drinks. We agreed to run her blood sugars higher during the programme to avoid hypoglycaemia as she would not have any glycogen stores to counteract it herself. Her husband was given in-depth advice on how to treat hypos with glucose or Hypostop if they occurred (Glucagon would not have been effective). We also agreed not to allow her blood sugars to go over 14 mmol/l because, although ketosis was desirable from the point of view of confirming fat burning, we did not want it to be in conjunction with marked hyperglycaemia, putting her at risk of ketoacidosis.


