Outcomes of an 8-week very low calorie diet undertaken by obese adults with type 2 diabetes

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Article points

1. Evidence is growing that very low calorie diets can improve management of type 2 diabetes among obese adults.

2. Psychology and dietetics can work together, with support from GPs, to develop and provide supported VLCD programmes in primary care.

3. Such innovative service development is valued by this group, and can improve glycaemic control and achieve weight-loss in the short term.

4. Further research is required to understand the significance of these improvements in the long term.

Key words

- Diabetic remission
- Obesity
- Very low calorie diet

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Obesity increases the risk of type 2 diabetes and the number of affected individuals is increasing. A growing body of evidence suggests that a very low calorie diet (VLCD) can improve body weight, glycaemic control and potentially result in diabetic remission. An 8-week VLCD programme was developed and delivered by a primary care psychology service, with input from dietetics and supported by local GPs. Eleven obese adult participants with type 2 diabetes completed the programme and outcomes for glycaemic control and weight loss are reported here.

Type 2 diabetes has now reached alarmingly high levels in the UK population and obesity is a contributing factor. Vetter et al (2009) report that approximately 30% of people undergoing bariatric surgery have concurrent type 2 diabetes.

Evidence suggests that losing 10% of original body weight may improve glycaemic control in people with type 2 diabetes, despite weight regain (Baker et al, 2009). Furthermore, there is evidence that type 2 diabetes is either resolved or markedly improved following bariatric surgery (84–98% for bypass procedures; 48–68% for restrictive procedures; Dixon et al, 2008; Baker et al, 2009; Buchwald et al, 2009; Vetter et al, 2009). It has been widely documented that this is primarily due to caloric restriction (Thaler and Cummings 2009; Vetter et al, 2009; Nannipieri et al, 2011).

Novel ideas have emerged to mimic the effect of surgery using less costly and risky alternatives, one of which is the very low calorie diet (VLCD). Findings from a recent VLCD study (Lim et al, 2011) have been promising in terms of improving glycaemic control among overweight and obese people with type 2 diabetes.

Background

A VLCD comprises 1.88–3.35 MJ/day (450–800 kcal/day) providing at least 50 g protein, essential fatty acids, daily requirements of trace vitamins and minerals (Baker et al, 2009). VLCDs are designed to reduce an individual's body fat, particularly visceral fat, which is thought to facilitate diabetic remission (Lim et al, 2011). VLCDs have the potential to normalise beta-cell function by reducing fat around the pancreas and liver triacylglycerol (Lim et al, 2011). Lim et al's (2011) results suggest that type 2 diabetes – once thought to be an irreversible and degenerative disease – can potentially be reversed by dietary change.

Attrition and poor adherence to prescribed dietary regimens result in the failure of many individuals to achieve weight-loss goals, limiting the effectiveness of such interventions (Huisman et al, 2010). A number of variables are associated with high attrition rates in diet programmes, including depression, stress, low motivation, low goal ownership and unrealistic weight loss expectations (Honas et al, 2003; Gill et al, 2012). Indeed, depression – which is more prevalent among people with diabetes than the general population – is commonly associated with poor glycaemic control, decreased compliance with therapy and increased risk of diabetes-related complications (Nouwen et al, 2010).

The need to incorporate psychological support within existing diabetes and weight management

services is apparent. This was reflected in an NHS Diabetes report (2010), which highlighted the significant psychological and emotional needs of people with diabetes and the importance of meeting these needs to promote self-care and wellbeing. A Cochrane report provides support for the effectiveness of group-based self-management interventions in improving fasting blood glucose and glycated haemoglobin levels, improving diabetes knowledge and reducing systolic blood and body weight (Deakin et al, 2005).

Aims

The aims of the present study were to determine whether an 8-week VLCD, in conjunction with psychological therapy, improved diabetes management by achieving weight loss and improving glycaemic control in obese adults with type 2 diabetes. A qualitative questionnaire was also undertaken to assess the acceptability of the programme to participants.

Method

A primary care-based psychology service in Swindon liaised with local GP surgeries and the local dietetic department to develop a VLCD programme – within the existing service provision – for obese (BMI >30 kg/m²) adults with type 2 diabetes.

Individuals who met the inclusion criteria (*Box 1*) were identified by the participating GPs and referred for assessment by a dietitian and a psychologist to determine their suitability for inclusion in the study.

The purpose of the psychological and dietetic assessment was to ensure individuals fully understood the VLCD, including what they could and could not eat, the structure and nature of the programme, and the psychological support available. The assessment also served to manage individuals' expectations. They were asked to identify current coping strategies and potential barriers to adhering to the diet.

Participants followed a diet of 800 kcal/day for 8 weeks, of which 600 kcal/day were from three meal-replacement sachets and 200 kcal/day from 240 g of non-starchy vegetables.

Body weight and fat mass, serum cholesterol, triglycerides, full blood count, ferritin, HbA_{1c},

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Box 1. Inclusion and exclusion criteria for the very low calorie diet programme run by the primary care-based psychology service in Swindon.

Inclusion criteria:
- Type 2 diabetes diagnosed within the 4 years prior to enrolment.
- Age 18–65 years.
- Diabetes managed by diet or metformin only.
- BMI >30 kg/m².
- HbA_{1c} <75 mmol/mol (<9%).

Exclusion criteria:
- Creatinine >120 µmol/L.
- Heart failure.
- Liver failure (or aspartate aminotransferase / alkaline phosphatase / alanine transaminase 3-times above upper limit of normal).
- Diabetes type other than type 2 (e.g. type 1 diabetes, secondary diabetes due to pancreatitis, maturity onset diabetes of the young, latent autoimmune diabetes of adulthood).
- Severe mental health condition (e.g. psychosis).
- Diagnosed eating disorder.
- Receiving steroid or insulin therapy.

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fasting blood glucose, alanine transaminase and gamma-glutamyl transpeptidase were recorded before and immediately after the 8-week diet programme, and periodically during follow-up (3, 6 and 12 months after completion of the diet). Data on medications being taken were collected at baseline, and 6 and 12-month follow-up.

All participants completed an anonymous, qualitative questionnaire (*Appendix I*) at the end of the 8-week diet. The questionnaire was designed by LIFT Psychology (Avon and Wiltshire Mental Health Partnership NHS Trust, Swindon) and sought the opinion of participants on the acceptability of the programme, including what they valued about it and what they felt should have been done differently.

Using a collaborative approach with the dietitians and psychologists, participants were taught to apply cognitive behaviour therapy (CBT)-based techniques, including managing unhelpful cognitions, relaxation, assertive communication, mindfulness and problem solving skills (Perri et al, 2001; Linde et al,

Page points
1. A primary care-based psychology service in Swindon liaised with local GP surgeries and the local dietetic department to develop a very low calorie diet programme for obese adults with type 2 diabetes.
2. Participants followed a diet of 800 kcal/day for 8 weeks, of which 600 kcal/day were from three meal-replacement sachets and 200 kcal/day from 240 g of non-starchy vegetables.
3. Participants were taught to apply cognitive behaviour therapy-based techniques designed to enable them to cope with the programme.

Page points

1. Four local GP surgeries referred 17 adults for assessment for inclusion in the programme; 12 met the inclusion criteria and were enrolled in the programme. Eleven participants completed the 8-week diet and attended the 3-month follow-up session.

2. A statistically significant decrease in mean blood glucose levels and HbA$_{1c}$ from baseline to study end were found, but significance was not maintained at 12-month follow-up.

3. A statistically significant decrease in mean BMI was recorded from baseline to study end, and was maintained at 12-month follow-up.

2006; Gregg et al, 2007). These strategies were designed to enable participants to cope with the programme, in addition to making longer-term lifestyle changes once the VLCD had ended.

Psychological support was provided in a group setting, 5 days a week for the first 2 weeks and twice a week thereafter until week 8. The meal replacement sachets were provided during these sessions.

Participants were invited to attend follow-up meetings facilitated by a dietitian and a member of the psychology service at 3, 6 and 12 months after completion of the VLCD. As well as data collection, participants were given the opportunity at these follow-up sessions to reflect on their experiences since the diet, including celebrating successes and problem-solving any challenges they were facing.

Analysis

Statistical analysis was carried out using SPSS (version 19). Variables were assessed in order to meet the assumptions underlying parametric testing. Variables (including transformed variables) that met the assumption of normality were analysed using paired samples t-tests.

Results

Four local GP surgeries referred 17 adults for assessment for inclusion in the programme.

Twelve individuals (6 female, 6 male; 7 receiving metformin; mean age 50.5 years) met the inclusion criteria and were enrolled in the programme. One individual discontinued the programme during the first week. The remaining 11 participants completed the 8-week diet and attended the 3-month follow-up session. The 6- and 12-month follow-up sessions were attended by seven and five participants, respectively.

A statistically significant decrease in mean blood glucose levels from baseline (7.27 ± 1.53 mmol/L) to study end (5.33 ± 0.74 mmol/L) was found ($t[10]=4.22$, $P<0.002$ [two-tailed]). Overall mean decrease in blood glucose levels during the study period was 1.93 mmol/L (95% confidence interval [CI], 0.914–2.957). Statistically significant improvements in mean blood glucose levels did not extend into the follow-up period (*Table 1*).

A statistically significant decrease in mean HbA$_{1c}$ from baseline (50.90 ± 6.93 mmol/mol [6.8%]) to study end (39.45 ± 2.94 mmol/mol [5.8%]) was also observed ($t[10]=6.20$, $P<0.001$ [two-tailed]). Overall mean decrease in HbA$_{1c}$ during the study period was 11.45 mmol/mol (95% CI, 7.34–15.56). Statistically significant improvements in mean HbA$_{1c}$ were maintained at 3-month follow-up (42.45 ± 4.39 mmol/mol [6.0%]; $t[10]=4.30$, $P<0.002$ [two-tailed]), at which point mean

Table 1. Participants' blood markers (*n*=11, unless otherwise shown).

Marker	Baseline (mean±SD)	Post intervention (mean±SD)	Difference (mean [95% CI])	3 month follow-up (mean±SD)	Difference (95% CI)	12 month follow-up (mean±SD)	Difference (mean [95% CI])
Glucose (mmol/L)	7.27±1.53	5.33±0.74	1.93 [0.91–2.95]*	6.30±1.50	0.96 [0.20–2.13]	7.21±2.27‡	0.14 [1.82–2.10]
HbA$_{1c}$ (mmol/mol)	50.90±6.93	39.45±2.94	11.45 [7.34–15.56]**	42.45±4.39	8.45 [4.07–12.83]*	44.00±4.04◊	7.28 [0.18–14.75]
Cholesterol (mmol/L)	4.62±0.66	3.36±0.90	1.26 [4.07–12.83]**	5.03±1.02	0.41 [1.08–0.26]	4.73±0.62‡	0.04 [0.35–0.43]
Triglycerides (mmol/L)	2.74±1.49†	1.20±0.45†	1.53 [0.65–2.42]*	2.50±1.32	0.35 [0.40–1.11]	2.22±1.86§	0.82 [0.27–1.40]*

CI, confidence interval; SD, standard deviation. †Data available for only 10 of the 11 participants. ‡Data available for only 8 of the 11 participants. ◊Data available for only 7 of the 11 participants. §Data available for only 5 of the 11 participants. *$P<0.05$; **$P<0.001$ (statistical comparisons conducted only for participants with complete data – this is reflected in the mean difference).

decrease in HbA_{1c} was 8.45 mmol/mol (95% CI, 4.07–12.83). Statistically significant improvements in HbA_{1c} were not maintained 12 months after completion of the programme (*Table 1*).

A statistically significant decrease in mean cholesterol levels from baseline to study end were seen (*P*<0.0001) but not maintained into the follow-up period (*Table 1*). Mean triglyceride levels decreased significantly during the study period (*P*<0.003) and, though significance was lost at 3-month follow-up, a statistically significant decrease in triglyceride levels was regained at 12-months post-VLCD (*P*<0.003; *Table 1*).

There was a statistically significant decrease in mean body weight from baseline (112.84 ±20.54 kg) to study end (96.24 ±17.63 kg; *t*[10]=14.44, *P*<0.001 [two-tailed]). Mean overall decrease in body weight was 16.6 kg (95% CI, 14.04–19.15). Statistically significant improvements in body weight were observed at 3- and 12-month follow-up (*Table 2*).

A statistically significant decrease in mean BMI was recorded from baseline (38.37 ± 4.35 kg/m²) to study end (32.74 ± 3.80 kg/m²; *t*[10]=19.73, *P*<0.001 (two-tailed)). Overall mean decrease in BMI was 5.62 kg/m² (95% CI, 4.99–6.26). Statistically significant improvements in BMI were maintained at 3-, 6- and 12-months follow-up (*Table 2*).

Three participants receiving metformin at baseline discontinued the therapy during follow-up, and one participant reduced their metformin dose. None of the participants who presented for follow-up commenced or increased metformin therapy during that period (*Table 3*).

The anonymous feedback questionnaires completed by participants at the end of the 8-week VLCD were overwhelmingly positive about the programme, especially regarding the CBT-based techniques learnt during the diet, as well as the social support provided by the group-based approach. Several participants described the programme as "excellent", and many explicitly valued the social outlet provided by the psychology-led group sessions in addition to the problem-solving skills taught during these. Many provided feedback that the group sessions were too frequent, and that one meeting per week would have sufficed.

Discussion

At the end of the 8-week VLCD, fasting blood glucose decreased significantly, and 10 of the 11 participants were within the non-diabetic range (as defined by the Joint British Societies [2005]). However, statistically significant improvements were not maintained in the long term. At 6- and 12-months follow-up, participants had experienced some weight regain – as is expected following a return to normal eating – although participants did not return to baseline body weight.

These results support previous findings by Lim et al (2011) that a VLCD undertaken over an 8-week period by people with type 2 diabetes can reduce body weight and cardiac risk factors (i.e. cholesterol) and improve glycaemic control. Important differences between the Lim et al (2011) study and the present study are that Lim et al do not present follow-up data, whereas the present

"Statistically significant improvements in BMI [following the 8-week very low calorie diet programme] were maintained at 3-, 6- and 12-months follow-up."

Table 2. Body weight and BMI of participants (*n*=11, unless otherwise shown).

Marker	Baseline (mean± SD)	Post intervention (mean±SD)	Difference (mean [95% CI])	3 month follow-up (mean±SD)	Difference (95% CI)	6 month follow-up (mean±SD)	Difference (95% CI)	12 month follow-up (mean±SD)	Difference (mean [95% CI])
Body weight (kg)	112.84± 20.54	96.24± 17.63	16.6 [14.04– 19.15]**	98.19± 18.85	14.65 [12.42– 16.88]**	99.25± 19.98◊	12.05 [8.15– 15.95]**	94.30± 19.00††	9.32 [5.19– 13.44]*
BMI (kg/m²)	38.37± 4.35	32.74± 3.80	5.62 [4.99– 6.26]**	33.33± 3.99	5.03 [4.34– 5.72]**	33.65± 4.30◊	4.15 [2.73– 5.50]**	33.78± 5.51§	3.32 [2.03– 4.60]*

CI, confidence interval; SD, standard deviation. ◊Data available for only 7 of the 11 participants. §Data available for only 5 of the 11 participants. ††Data available for only 4 of the 11 participants. *P<0.05; **P<0.001 (statistical comparisons conducted only for participants with complete data – this is reflected in the mean difference).

Table 3. Summary of participants' medication regimens.

P	Pre-VLCD	6-month follow-up	12-month follow-up
1	Blood pressure medication; cholesterol medication	Stopped blood pressure medication; stopped cholesterol medication	Stopped blood pressure medication; stopped cholesterol medication
2	Metformin	Reduced metformin dose	Reduced metformin dose
3	Metformin	Still taking same dose of metformin	Still taking same dose of metformin
4	Metformin	ND	Still taking same dose of metformin
5	Metformin	Stopped metformin	ND
6	No medication	No medication	ND
7	Metformin	Stopped metformin	ND
8	Metformin; blood pressure medication	ND	Stopped metformin; reduced dose of blood pressure medication
9	No medication	No medication	ND
10	No medication	ND	ND
11	Metformin	ND	ND

ND, no data; P, participant number; VLCD, very low calorie diet.

study provides data from 3, 6 and 12 months following completion of the VLCD. Furthermore, Lim et al's (2011) participants had a lower mean BMI at baseline than those in the present study ($33.6 \pm 1.2\,kg/m^2$ vs $38.37 \pm 4.35\,kg/m^2$).

Although the improvements in glycaemic control were not maintained at 12-month follow-up in the present study, several participants' medication had been reduced or stopped over this timeframe and no new medications were introduced or doses increased.

Participants' positive feedback about the programme (i.e. the social support provided by the group-based sessions and the psychological support tools learnt) demonstrates the acceptability of this intervention for this client group. It also appears to facilitate adherence to the VLCD and long-term lifestyle changes. This, alongside dietary and psychological support, can be provided within a primary care setting with support from GPs.

Conclusion

There is potential to improve health and reduce prescription costs to the NHS through the implementation of VLCDs among obese people with diet- or metformin-managed type 2 diabetes, which may be a preferable alternative to bariatric surgery for many. However, futher research involving larger populations and long-term follow-up are needed to demonstrate in which BMI bracket VLCD is most effective and to better understand the sustainability of the initial improvements in glycaemic control. ∎

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"There is potential to improve health and reduce prescription costs to the NHS through the implementation of very low calorie diets among obese people with diet- or metformin-managed type 2 diabetes."

Appendix I. The anonymous, qualitative questionnaire delivered at the end of the 8-week diet. The questionnaire was designed by LIFT Psychology (Avon and Wiltshire Mental Health Partnership NHS Trust, Swindon) and sought the opinion of participants on the acceptability of the programme.

Please help us to improve this course by answering these questions. Please be honest with us – and do not write your name on this questionnaire.

1. Overall, how did you find the VLCD programme? _____

2. What did you find most helpful about the group sessions? _____

3. What did you find least helpful about the group sessions? _____

4. How welcome did you feel?

     0   1   2   3   4   5   6   7   8

Not at all   Very welcome

5. How could the programme have been improved? _____

Thank you for your help.