

Low-calorie diets in the management of type 2 diabetes mellitus

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Type 2 diabetes mellitus is common, disabling and expensive, despite improved glucose-lowering management and guidelines. Its dominant cause is weight gain, with ectopic fat accumulation in vital organs, reflected by a large waist circumference. Addressing the underlying cause, by low-calorie formula diets and integrated support for long-term weight-loss maintenance, produces remissions in almost half the treated population.

Type 2 diabetes mellitus (T2DM) is going through an identity crisis. Until the past year or two, it was regarded as a disease of the endocrine system, the lesser sibling of type 1 diabetes mellitus. It was frequently referred to as ‘mild’ or ‘maturity onset’ diabetes, with patients being reassured that they had ‘a touch of diabetes’ and merely needed to avoid foods containing high levels of refined sugar and/or take some tablets that would control their blood levels of glucose.

As recently as 40 years ago, that picture was generally true. T2DM was largely confined to the elderly and did not appear to shorten life or result in many clinical problems. Insulin was very rarely required and an annual review was mainly a social occasion.

The T2DM epidemic

Steadily, the prevalence increased, so management was shifted from endocrinology clinics to general practice. However, the prevalence increased largely because age of onset fell, and so, with longer duration of hyperglycaemia and subsequent damage to small blood vessels, an appalling catalogue of progressive, painful and disabling vascular complications has emerged. Guidelines for pharmacotherapy were stepped up to improve the control of blood levels of glucose. These measures have delayed the onset of microvascular complications to a degree, but with worrying mortality hazards as a result of hypoglycaemia. The usual target HbA_{1c} level of <7 mmol/l, too infrequently achieved, is not within the normal range and still indicates active, progressive disease. T2DM now affects 5–10% of adults in Western populations and accounts for 10% of total NHS health-care expenditure in the UK and 14% in the USA¹. These figures are despite people with T2DM dying 3–8 years earlier than others, depending on age of onset¹.

The solution was under our noses. It has been known for generations that weight gain is the dominant cause of T2DM and that susceptible people are those who tend to store excess body fat in ectopic sites. A large waist circumference is an important guide and tool for screening

to trigger preventive action; it reflects lipid accumulation in organs such as muscle, heart, liver and pancreas. Filled with fat, these vital organs fail to function normally. The liver exports too much glucose and VLDL, muscle fails to oxidize glucose and fat, and the normal pancreatic first-phase insulin response is lost. The net result, the metabolic syndrome, progresses to multisystem metabolic failure, and a range of progressive vascular complications. These complications are not reversible; however, the earlier disease process of T2DM should be reversible. That disease process, driven by ectopic fat accumulation, is none other than the disease process of obesity in susceptible individuals (probably predisposed by genetic and/or epigenetic factors)².

It is no small wonder that drug treatments to lower blood levels of glucose have had such limited effects on clinical outcomes if the underlying disease process is left to continue (or is even aggravated by insulin and sulfonylureas, which promote weight gain). The logical treatment of T2DM is the management of obesity, but with greater urgency than usual, to try to arrest clinical deterioration.

Benefits of low-calorie diets

A number of pieces of evidence suggested that to reverse T2DM into a non-diabetic state, and potentially avoid complications, usually requires intentional weight losses >15 kg. The metabolic effect of this weight loss is consistent, resulting in remission for 70–80% of people with T2DM, without requiring the extreme weight losses targeted by bariatric surgery³, and it is associated with extended survival⁴.

Losing 15 kg still leaves most patients considerably overweight, but it exceeds the potential of conventional dietetic interventions. Research has now refuted the long-held beliefs that rapid weight loss (for example, with very-low-calorie diets (VLCD)) is inevitably followed by complete weight regain^{5,6}. People who lose weight most rapidly actually do better in the long term, with studies also demonstrating improved retention in this group⁷ — people remain more engaged with an intervention that ‘does what it says on the tin’. Moreover, weight losses at

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12 months and beyond are the same with formula diets containing 800–900 kcal per day as with the more restrictive VLCDs (defined internationally as <800 kcal per day). For the initial rapid weight-loss phase, it is possible to design food-based diets containing most essential micro-nutrients within 800 kcal, but most patients prefer ‘total diet replacement’ using a commercial formula diet, made up of soups and shakes. The ‘total diet replacement’ phase, for 8–12 weeks with no normal meals, foods or drinks, with a complete step away from the temptations of usual foods and eating habits, is a key factor for adherence and successful substantial weight loss.

Formula diets are nutritionally complete and their safety records are excellent, so close medical supervision is unnecessary. Meta-analyses show that weight regain after using a formula ‘total diet replacement’ approach is seldom complete⁵, and rapid weight loss actually leads to better long-term outcomes than conventional diets or using formula ‘meal replacements’ to replace some but not all meals. Importantly, unlike most conventional diet or drug methods, using total diet replacement is equally effective for weight loss in people who are overweight with or without T2DM⁸.

A low-calorie diet alone cannot resolve T2DM. Most people with obesity can lose weight. However, maintaining the weight loss is challenging for a person who returns to the same environment and behaviours that produced their weight gain, coupled with endocrine and metabolic adaptations that promote regain. We do not yet have the final answer for successful weight-loss maintenance⁹, but professional support is valuable to guide the switch from a low-calorie formula regimen to the introduction of ordinary foods and drinks for weight maintenance. It is extremely difficult to reject a lifetime’s usual habits and adopt someone else’s normality.

The DiRECT intervention was delivered entirely within routine primary care. The intervention was successful in achieving remissions of T2DM for 46% of participants at 1 year, in part because it used an integrated, carefully structured programme with trained professional support (Counterweight-Plus)⁶. Stopping all anti-diabetes medication on day 1 was welcomed and generated a sense of commitment to the formula total diet replacement. The programme also introduced, from the outset, a steady focus on developing personal strategies for permanent behavioural change, using elements from proven theory-based methods. Food reintroduction was gradual, with stepped increases in meals while reducing the numbers of formula sachets, rather than switching suddenly to a completely food-based diet. Finally, patients were offered a much-valued secret weapon. Recognizing their well-founded fears that they were likely to meet life problems and experience weight regain, the programme includes a firm commitment to provide relapse management (a ‘rescue plan’). Restoring weight loss after >5 kg regain is hard, so patients were asked to seek help if they regained >2–4 kg, to address

factors behind the regain and then undertake a further period of partial or full total diet replacement to restore their weight loss. Up to half of patients require a ‘rescue plan’ to keep on track¹⁰.

Seeking remission from T2DM is becoming the preferred first-line of management. This strategy has the potential to avoid both pathology and costs. The complete cost of delivering the DiRECT intervention to an individual was £1,067, which compares with the average annual health-care cost of an individual with T2DM of ~£2,800, so this is not an expensive new treatment. The cost per remission achieved was ~£2,500, and there were many other benefits, including for those who did not reach remission¹.

Conclusion

A low-calorie diet is extremely effective in reversing obesity and secondary T2DM, and on present evidence, compared with less successful conventional diets, it is necessary in order to establish sufficient weight loss. However, a low-calorie diet is not sufficient alone; for long-term success, people need a composite for ward-looking integrated programme directed at long-term maintenance. It needs to be delivered by trusted professionals in a setting where the health consequences of T2DM can be discussed openly and where ‘failure’ to lose sufficient weight is understood and managed sympathetically. The results amply justify the major shifts in health-care budgets already announced in the UK, but can still be improved. With future research and development, we must learn how to provide the necessary weight loss to achieve T2DM remission for more patients, and develop better methods to maintain remissions for longer.

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Competing interests

M.E.J.L. has consulted for Counterweight Ltd, with fees paid to the University of Glasgow.