

The DIAMOND study: plain English summary of the results

Why we did this research

Type 2 diabetes is partly caused by too much body fat. It is diagnosed when the level of glucose in people's blood is too high. Insulin, a hormone secreted by the pancreas, usually helps to lower blood glucose, but if there is too much body fat this can reduce the production of insulin. Too much body fat can also stop muscles and other tissues from responding normally to insulin, so blood glucose levels rise sharply after a meal and remain high.

High blood glucose can cause serious health problems if it is left untreated, including blindness, kidney damage and heart disease. Most people with type 2 diabetes are offered drug treatments to help control their blood glucose levels and will need to continue this treatment for life. About 1 in 16 people in the UK are affected by type 2 diabetes, and treating it and the health problems it causes costs the NHS nearly £12 billion per year.

Recent research has shown that it may be possible to treat people with type 2 diabetes with an intensive weight loss programme. Reducing body fat restores the function of insulin and a proportion of people no longer need to take any diabetes medication.

This type of treatment is known as a total diet replacement (TDR) programme. TDRs provide about 800 calories per day in the form of commercially produced soups, shakes and bars, but little or no 'real' food. People use these products for 2–3 months and then gradually return to 'real' food. After 1 year they are, on average, about 10 kg lighter and almost half of the people who follow the programme are in remission from their diabetes.

However, these types of programme are not routinely available in the NHS, so few people are offered them. Instead, most people with diabetes are given dietary advice by their GPs and diabetes nurses. Practitioners and patients have been asking whether or not the benefits of TDR programmes can be achieved with a low-energy food-based diet instead.

But before we can truly answer that, we needed to

develop a programme to provide people with dietary advice and support. Then we needed to know if was possible to train non-specialist GPs and practice nurses to deliver such a programme and for them to support people to achieve substantial weight loss. We conducted a 'feasibility study' to answer these questions and to help us decide whether we could run a bigger trial to test the effect of a low energy, food-based programme on health in the longer term. It is only after a big trial that we will be able to see if this programme is a good treatment for type 2 diabetes, but the first step is to see if such a trial is possible.



What we did

33 people with type 2 diabetes, who were also classified as overweight, took part in our research.

One third of people were randomly selected to receive 'usual care' from their doctors and nurses including advice to eat a healthy, balanced diet.

The remaining two thirds of people were asked to try our DIAMOND (Dietary Approaches to the Management Of type 2 Diabetes) programme to reduce their energy intake to 800–1000 calories per day for eight weeks. To achieve this target, we asked people to remove all the major sources of carbohydrate from the diet, with only modest amounts of dairy products and a little fruit, and to adhere to strict portion limits for other foods to achieve the energy target. To support them to



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do this, patients had longer and more frequent appointments with specially trained nurses who provided advice and encouragement. We also gave the patients written resources including recipe cards and meal planners, guidance on portion sizes and how to use food labels.

This low energy, low carbohydrate diet leads to rapid weight loss, but is very demanding. People were asked not able to eat any sugary foods and remove all starchy carbohydrates from their meals. After 8 weeks, people were allowed to gradually increase their energy intake until their weight stabilised. They ate slightly larger portions of food and introduced some high-fibre carbohydrate foods back into their meals.

Even though this was only a small group of people we wanted to see the effect of the diet on their diabetes. We suggested that people in the intervention group should stop most of their diabetes medications at the start and we measured the levels of HbA1c in their blood to check how well their blood glucose was controlled. HbA1c tells us about the level of blood glucose over the past 12 weeks- a long-run average measure.

Finally, consultations were recorded (with permission) to check whether the programme was delivered correctly. We also asked patients, nurses and doctors to understand their experiences of the programme.

What we found

The main question this research was looking to answer was whether a trial in primary care (GP surgeries) would even work. Could nurses deliver the programme and would patients and nurses find it acceptable?

In advance we set ourselves specific targets. We found that we could recruit patients and that all patients in the weight loss programme were willing to attempt the diet. We found that nurses delivered the programme well and thought they could do this in their routine practice. Patients were very positive about the experience and everyone attended their final follow up session after 12 weeks.

We also found that people on the low-energy diet

lost 7.5kg (just over 1 stone) more than people in the 'usual care' group. They had a 15.7mmol/mol reduction in HbA1c compared to the usual care group, suggesting their blood glucose was well controlled, even though they had stopped some of their diabetes medications. This drop is larger than most medications achieve.

What this means

Firstly, this research shows that it would be feasible to recruit patients and carry out a much larger trial of this low energy, low carbohydrate programme. Secondly, it gives us hope that this intervention will lead to successful weight loss and improved blood glucose control for people with type 2 diabetes living with overweight or obesity.

To our knowledge this is the first trial to try to attempt restricting people's calorie intake to levels similar to total diet replacement programmes, but using 'real' food and with a support programme that can be offered by non-specialists in routine primary care consultations.

But this study is far from the last word. It only lasted 12 weeks and with few people. Our future work will need to look at a much larger number of people to see if our preliminary findings hold up, and to examine the effects in the longer term. We need a bigger trial to test if this programme can help people achieve remission from their diabetes and if this treatment should be offered by the NHS. Until the big trial is complete we cannot make new recommendations about this type of treatment for people with type 2 diabetes.

Reference:

Morris, E. , Aveyard, P. , Dyson, P. , Noreik, M. , Bailey, C. , Fox, R. , Jerome, D. , Tan, G. D. and Jebb, S. A. (2019), A food-based low-energy, low-carbohydrate diet for people with type 2 diabetes in primary care: a randomised controlled feasibility trial. *Diabetes Obes Metab.* Accepted Author Manuscript. doi:10.1111/dom.13915

