A LOW-ENERGY FORMULA DIET PROGRAMME AND TYPE 2 DIABETES REMISSION SUPPORTING YOUR PATIENTS
With the initial results of the DiRECT (Diabetes Remission Clinical Trial) being published at the end of 2017 and the consequent widespread media coverage, the question “How do I reverse my Type 2 diabetes?” is likely to feature at many clinic appointments. So what should we, as healthcare professionals say? And how can we support Type 2 diabetes remission?

Pav Kalsi, Senior Clinical Advisor at Diabetes UK, spoke to Naomi Brosnahan, one of the dietitians who is involved in the DiRECT trial, to get some insight into the details of the study. They have now put together some guidance for healthcare professionals working with people who are interested in putting their Type 2 diabetes into remission.

**Why remission and not reversal or cure?**
It's important to use the opportunity to set the record straight at the outset and encourage the more correct term of remission. Remission indicates that blood glucose levels now fall into the normal range and that diabetes medication can be stopped; reversal gives the impression that Type 2 diabetes no longer exists and there is no risk of diabetes-related complications.

At the moment, we don’t have the evidence to say that Type 2 diabetes can be completely reversed and that people are clear of complications. That’s why it’s important to encourage people who are in remission to continue to attend their diabetes appointments and be monitored for signs of complications, especially because some of these may have started to develop before remission was achieved.

Equally important is the message around keeping to the new lower weight where blood glucose is in the normal range, for weight regain is linked with return of higher blood glucose levels and the return of diabetes status and associated need for medications.

**Can anyone with Type 2 diabetes do the study intervention?**
While the programme used in the study is available to be commissioned by the NHS, it is also available privately for those who wish to lose weight and put their Type 2 diabetes into remission. The Counterweight-Plus programme was used in the DiRECT study, but other commercially available programmes are available. The total diet replacement phase of the programme should not be viewed as a quick fix. It can be a real challenge for some to stick to and may not be right for everyone.

A big part of the study was the level of support the participants received from trained healthcare professionals, particularly around reintroduction of meals and the all-important weight loss maintenance phase. It is, therefore, essential to offer fairly intensive support for anyone who is undergoing this type of programme.

The study itself included adults between the ages of 20–65 who had been diagnosed with Type 2 diabetes within the last six years with a BMI 27–45kg/m². Type 2 diagnosis was confirmed and HbA1c checked for eligibility—ie, HbA1c ≥48mmol/mol (or ≥43mmol/mol for those on anti-diabetes medication).

There are some people for whom this treatment may not be appropriate or safe, so clinical judgement is needed. In the study some groups of people were excluded, such as people with an eating disorder, or medical conditions that contraindicate a formula diet (see study for full exclusion criteria). People taking insulin were also not included in the study.

Another key consideration is assessing an individual’s motivation. The research dietitians involved in the DiRECT study used behaviour change techniques to ensure patients achieve long-term weight maintenance and remission. Hence the study continues to see participants for a full two years. Alternatively, patients could be supported to follow a food-based 800–900kcal/day diet plan with support.

**What does the diet involve?**
Since remission of Type 2 diabetes was closely linked to weight loss, the main approach used in DiRECT was to aim for weight loss of 15kg or more in a relatively short time period (compared with other weight management strategies) with an emphasis on weight loss maintenance thereafter.

DiRECT used a structured programme with three main stages: weight loss achieved with total diet replacement, food reintroduction and then finally the weight loss maintenance phase. During all these stages, support from a healthcare professional (practice nurse or dietitian) was given, with weekly or fortnightly appointments during the initial weight loss phase and monthly during the weight maintenance stages.

The total diet replacement stage involved having 825–853kcal per day in the form of shakes and soups (in place of usual meals) for 12–20 weeks. DiRECT used the Counterweight-Plus programme, which includes nutritionally complete total diet replacement sachets. There are other commercial meal replacements available. However, the DiRECT results have shown that, for this approach to work effectively, the level of support from healthcare professionals using behavioural change principles is necessary.

The Counterweight-Plus programme provides an accompanying support mechanism (nurse or dietitian) and is underpinned with behavioural change techniques to ensure patients achieve long-term weight maintenance and remission. Hence the study continues to see participants for a full two years. Alternatively, patients could be supported to follow a food-based 800–900kcal/day diet plan with support.
The Counterweight-Plus Programme Structure

**Total Diet Replacement**
- 12 weeks
- Weekly/Fortnightly Appointments

**Food Reintroduction**
- 6 weeks
- Fortnightly Appointments

**Weight Loss Maintenance**
- 86 weeks
- Monthly Appointments

**Rescue Plan**
- 2kg+ weight regain
  - Food Reintroduction
  - Rescue Plan
  - 4 weeks

- 4kg+ weight regain
  - OR
  - <15kg below starting weight
  - OR
  - HbA1c>48mmol/mol
  - Total Diet Replacement
  - Rescue Plan
  - 4 weeks

Continue on Total Diet Replacement up to 20 weeks if > 15kg weight loss is not achieved.
from a diettian to ensure it is nutritionally complete. A caution here is that food-based plans do not have the same level of evidence at this point.

During the total diet replacement stage, it is also important to include enough fluids – aiming for 2.25l/day and to be regularly physically active, as a common side effect during this stage is constipation. In the study, people with constipation were prescribed a fibre supplement such as Fybogel.

The food reintroduction stage involved a gradual transition to a food-based diet based on healthy eating principles (using the Eatwell Plate). The important consideration is that the diet is tailored to the individual, to consider lifestyle elements to ensure long-term sustainability. The main aim of this phase is to ensure that any weight lost stays off. For those that needed it, there was an element of flexibility during this phase (within the protocol-defined limits of two to eight weeks) before completely switching to a full food-based diet. Patients were reviewed fortnightly.

The weight loss maintenance phase involved structured support to help maintain long term weight loss and prevent weight regain. Participants followed a food-based diet, although they were given the option of using one sachet of meal replacement per day for the duration of weight loss maintenance period. Participants were reviewed monthly by their healthcare professional and encouraged to weigh themselves weekly, monitor their food intake and behaviours around eating and maintain regular physical activity levels.

**Side effects**

The two serious adverse events reported in the study were biliary colic and abdominal pain, potentially linked to the total diet replacement phase. Other transient side effects included constipation, headache, increased sensitivity to the cold and dizziness, that usually went away after a short time and, besides constipation, no other side effect required treatment.

**Support from healthcare professionals**

Key to the success of this programme and especially the weight loss maintenance stage, is the support from healthcare professionals and an element of flexibility. In the study, behavioural change methods were used, with provision of printed support materials. Participants were encouraged to develop strategies to avoid regaining weight, such as planning ahead for holidays and social occasions. Individual flexibility was incorporated into the study, in order to improve the likelihood of maintaining weight loss and remission. ‘Rescue’ or relapse-management plans were also offered to those who regained weight or for those whose diabetes had returned (HbA1c ≥48mmol/mol) during the weight loss maintenance stage. This included using total diet replacement or meal replacement plans again, offering orlistat with meals and a review of motivation, barriers and general behaviour relating to diet and physical activity.

**Medication**

In the trial, all oral antidiabetic and antihypertensive medications were stopped when participants started the weight management programme. Blood glucose and blood pressure was monitored throughout the study and medication was reintroduced if necessary using national clinical guidance. In practice, a joint clinic with a GP, nurse and diettian may be useful to supervise any medication changes.

**Conclusion**

As we enter a new era of managing Type 2 diabetes, the hope is that findings from DiRECT will lead to a new treatment paradigm. At diagnosis of Type 2 diabetes (an optimal intervention time point), evidence-based programmes will be funded and made available for healthcare professionals to achieve diabetes remission, as opposed to the current approach of focusing on optimal medical management of the condition. The next stage in the journey towards Type 2 diabetes remission is the eagerly awaited publication of the two-year outcomes from the DIRECT study.

**REFERENCES:**


Research roundup: www.diabetes.org.uk/up-low-cal