

Weight loss can put Type 2 diabetes into remission for at least two years, reveal latest findings from DiRECT

- More than a third of participants in remission two years after weight management programme.
- Of those in remission after one year, 70% stayed in remission.
- Remission closely linked to weight loss: two thirds of those who lost 10 kilos or more in remission after two years.
- Weight management programme also resulted in better quality of life and reduced need for diabetes medications, compared to standard care.

More than a third (36%) of people with Type 2 diabetes who took part in a weight management programme delivered in NHS primary care are in remission two years later, the latest findings of the Diabetes Remission Clinical Trial (DiRECT) have revealed.

The second year results of the trial, funded by Diabetes UK and led by experts at Newcastle University and the University of Glasgow, were announced today at Diabetes UK's Professional Conference and published in *The Lancet Diabetes & Endocrinology*.

Professor Roy Taylor – who co-led the trial with Professor Mike Lean – said the findings 'pull down the curtain on the era of Type 2 diabetes as an inevitably progressive disease'.

These new results build on the globally-reported findings presented at the International Diabetes Federation in December 2017, which showed that 46% of participants were in remission after one year. A year later, 70% of those participants are still in remission.

The results confirm that – as with the first year results – remission is closely linked to weight loss; 64% of participants who lost over 10 kilos were in remission at two years. Participants regained some weight, as expected, between the first and second year. However, those in remission after one year who stayed in remission had a greater average weight loss (15.5 kilos) than those who did not stay in remission (12 kilos).

Participants were defined as in remission if they had long-term blood glucose levels (HbA1c) of less than 48mmol/mol (6.5%) without needing to use any Type 2 diabetes medications.

As well as resulting in remission for many participants, the programme led to a drop in blood glucose levels and fewer diabetes medications across the whole intervention group. The average HbA1c fell from 60mmol/mol at the start to 54mmol/mol at the end of year two. Diabetes medication use dropped from 75% of the group to 40%.

In comparison, the average HbA1c remained similar (58mmol/mol vs 59mmol/mol) in those receiving standard care – the control group – and the proportion of people taking medications increased from 77% to 84%.

Quality of life scores increased across both groups, but those in the intervention group reported a larger improvement (10 point increase versus 2.5 point increase).

Understanding why significant weight loss results in remission of Type 2 diabetes is at the heart of DiRECT. Detailed studies have so far revealed that weight loss can lead to reduced levels of fat inside the pancreas, which in turn associated with the recovery of pancreas function and insulin production.

By understanding the biology of remission, Professors Taylor and Lean believe it should be possible to provide better care for people diagnosed with Type 2 diabetes in the future.

Professor Roy Taylor, Director of Newcastle University's Magnetic Resonance Centre, and coprimary investigator of the DiRECT trial, said:

"These results are a significant development, and finally pull down the curtain on the era of Type 2 diabetes as an inevitably progressive disease.

"We now understand the biological nature of this reversible condition. However, everyone in remission needs to know that evidence to date tells us that your Type 2 diabetes will return if you regain weight.

"Even during the second year of freedom from Type 2 diabetes there was a highly suggestive difference in major complications of diabetes. The numbers are still small at the moment, and further information on this must be gathered during the planned longer term follow up."

Professor Mike Lean, Head of Human Nutrition at Glasgow University, diabetes specialist physician at Glasgow Royal Infirmary, and co-primary investigator of DiRECT, said:

"Proving in DiRECT that Type 2 diabetes can be put into remission for two years in more than two thirds of people, if they can lose more than 10 kilos, is incredibly exciting. Achieving that entirely in NHS primary care is vital.

"People with Type 2 diabetes and healthcare professionals have told us their top research priority is 'can the condition be reversed or cured'. We can now say, with respect to reversal, that yes it can. Now we must focus on helping people maintain their weight loss and stay in remission for life.

"If allowed to progress, Type 2 diabetes becomes devastating. Our work has also shown that this weight management programme is relatively inexpensive when compared to the long-term management of Type 2 diabetes, and this provides a compelling case for shifting resources to offer remission-based care."

Dr Elizabeth Robertson is Director of Research at Diabetes UK. She said:

"These results further challenge the perception that Type 2 diabetes needs to be a lifelong condition for everyone diagnosed with it.

"Remission of Type 2 diabetes can be life changing; DiRECT offers one potential solution, we are committed to working with the researchers and the NHS to ensure these exciting findings reach people with Type 2 diabetes as soon as possible.

"But we know Type 2 diabetes is a complex condition, and this approach will not work for everyone. That's why we're continuing to invest in further research, to understand the biology underlying remission and find ways to make remission a reality for as many people as possible."

58 year-old Joe McSorley from Glasgow, Network Engineer at BT, didn't have any symptoms before being diagnosed with Type 2 diabetes.

His diagnosis came as a huge shock, and the thought of being on medication for life led him to take part in DiRECT. Joe's case is an exceptional one; since achieving remission, Joe's life has changed dramatically and he is now planning to become a personal trainer – which he'll do when he retires in two years' time. To this day, Joe does not need to take any of his diabetes medications.

He said: "It's been a life-changing experience for me in many ways. One of the biggest changes has been the exercise which I now do on a daily basis without thinking about it twice. I'd have never imagined that I would be as fit at my age as I was at 21 or that my blood pressure would ever be similar to that of an athlete.

"It was a difficult decision to take but it was the right decision as my life has changed so much. The way I used to look at diabetes was starting to have a detrimental effect on my life – looking back, there was a certain amount of denial when I got on the trial. DiRECT gave me the direction I was lacking and pushed me to make the changes that I was due making in my life."

Six months after first being diagnosed with Type 2 diabetes in 2011, Isobel Murray, 67 from North Ayrshire, was put on medication.

This was increased with each visit to the doctor, due to her feeling more and more unwell. This all changed in 2014 when, 17 weeks into the trial, Isobel went into remission. Four and a half years later, Isobel is still in remission and does not need any diabetes medication.

She said: "When I was first told that my diabetes went into remission, I felt absolutely ecstatic. Four and a half years later, that feeling is still with me. Over the last few years I've been able to lead a normal life again.

"It only took a few months to do the plan and to get my life back – it was worth every minute. I feel ten years younger now and I will do everything in my power to never go back to how things were before; I still keep a food diary from time to time to make sure I stay on track, along with going to the gym and doing a lot more walking."

ENDS

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Post-embargo link to the publication: Final accepted draft, prior to editing and corrections.pdf

NOTES TO EDITORS

About Type 2 remission

Type 2 diabetes remission means that a person no longer has high blood glucose levels, and does not need to take diabetes medications. We recommend that people who are in remission still get their

annual health check-ups, to check that their Type 2 diabetes hasn't returned, particularly if they have regained weight, and they haven't developed any complications.

Weight loss surgery has been shown to put Type 2 diabetes into remission in 30 to 60 percent of cases, but this is not suitable for everyone.

About DiRECT

DiRECT aims to find an effective way to put Type 2 diabetes into remission for the long term. The trial is delivered through 49 GP practices in Scotland and Tyneside to find out if the structured weight management programme can be delivered in a primary care setting.

A detailed economic analysis of the DiRECT intervention, published in *The Lancet Diabetes and Endocrinology* in 2018, showed that the cost of providing the entire programme for 12 months was \pounds 1,067 per patient, and the cost per case remission was \pounds 2,564. The current average cost to the NHS of managing Type 2 diabetes is \pounds 2,801 per year.

Of the 298 people who took part in DiRECT, half received standard diabetes care from their GP and half received a structured weight management programme. The programme included a low-calorie, nutrient-complete diet (around 800 calories per day) for between 12 and 20 weeks, support from a nurse or dietitian to reintroduce healthy foods into the diet, and long-term support to maintain weight loss. Medications for Type 2 diabetes and blood pressure were stopped at the beginning of the programme and reintroduced as necessary.

Each GP practice is randomised to either deliver the weight management programme or best available care. People aged 20-65, who have had Type 2 diabetes for less than six years, were recruited. They had a body mass index (BMI) between 27 and 45 kg/m2. The recruitment was completed in August 2016, with 306 people signing up to the trial.

People from ethnic minorities, such as South Asian and Black Caribbean origin, are at a higher risk of Type 2 diabetes. While DiRECT participants represented the typical population from the geographical regions of the study, more research is needed to understand remission in the context of ethnicity and family history of Type 2 diabetes.

DiRECT involved the Counterweight Plus weight management programme. The low-calorie mealreplacement product was supplied without charge by Cambridge Weight Plan, as part of the Counterweight Plus structured weight management programme. Counterweight Plus was developed by Counterweight Ltd. in association with the University of Glasgow, and part-funded by the Scottish Government Health Department. The Counterpoint study, previously funded by Diabetes UK, also informed the design of DiRECT.

Remission and weight loss were the primary outcomes of DiRECT. Quality of life was a secondary outcome and was measured using the EuroQol 5 Dimensions (EQ-5D-3L). The EQ-5D-3L system comprises of five dimensions: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. The participants rate their health on a vertical, visual scale between 'best imaginable health state' and 'worst imaginable health state'.

More information about DiRECT can be found at <u>www.diabetes.org.uk/direct</u>, and <u>www.directclinicaltrial.org.uk</u>.

About Diabetes UK

- 1. Diabetes UK's aim is creating a world where diabetes can do no harm. Diabetes is the most devastating and fastest growing health crisis of our time, affecting more people than any other serious health condition in the UK more than dementia and cancer combined. There is currently no known cure for any type of diabetes. With the right treatment, knowledge and support people living with diabetes can lead a long, full and healthy life. For more information about diabetes and the charity's work, visit <u>www.diabetes.org.uk</u>
- 2. Diabetes is a condition where there is too much glucose in the blood because the body cannot use it properly. If not managed well, both Type 1 and Type 2 diabetes can lead to devastating complications. Diabetes is one of the leading causes of preventable sight loss in people of working age in the UK and is a major cause of lower limb amputation, kidney failure and stroke.
- 3. People with Type 1 diabetes cannot produce insulin. About 10 per cent of people with diabetes have Type 1. No one knows exactly what causes it, but it's not to do with being overweight and it isn't currently preventable. It's the most common type of diabetes in children and young adults, starting suddenly and getting worse quickly. Type 1 diabetes is treated by daily insulin doses taken either by injections or via an insulin pump. It is also recommended to follow a healthy diet and take regular physical activity.
- 4. People with Type 2 diabetes don't produce enough insulin or the insulin they produce doesn't work properly (known as insulin resistance). Around 90 per cent of people with diabetes have Type 2. They might get Type 2 diabetes because of their family history, age and ethnic background puts them at increased risk. They are also more likely to get Type 2 diabetes if they are overweight. It starts gradually, usually later in life, and it can be years before they realise they have it. Type 2 diabetes is treated with a healthy diet and increased physical activity. In addition, tablets and/or insulin can be required.

For more information on reporting on diabetes, download our journalists' guide: <u>Diabetes in the News:</u> <u>A Guide for Journalists on Reporting on Diabetes</u> (PDF, 3MB).