

# Transform Diabetes Study: 1 to 1 Programme

**A programme of diets and behaviour change to support and reverse your type 2 diabetes**

## **About this study**

Type 2 diabetes is one of the most common long-term conditions we face in the UK, and often people from Black, Asian and Minority Ethnic groups are at higher risk of type 2 diabetes. If left unmanaged, high blood sugar levels can cause several health problems, so the aim of diabetes management is to try to control blood sugar levels within healthy limits to prevent these complications.

Diabetes is normally managed by a combination of diet, lifestyle and medication with the aim of controlling blood sugar levels. Recent research has shown that certain diets can lead to significant weight loss and reduce blood sugar, in some cases to below the level associated with diabetes, called putting your diabetes into remission.

The Transform Diabetes Study is offering people from 9 GP practices in Southwark the opportunity to follow a choice of diets that could achieve a significant improvement in blood sugar levels or diabetes remission. All participants will be supported for one year by a Diabetes Specialist Dietitian.

The Transform Diabetes Study will assess how successful the intervention is at improving the health of people with type 2 diabetes in South London, and the learning will be used to design future programmes. The study will measure outcomes such as weight and blood sugar levels and will also explore your opinions and experiences to help us to understand how successful the programme was and how it could be improved.

## **How do I find out more?**

You will be invited to attend a webinar or watch a recording of the webinar which will tell you about the three dietary interventions you can choose from. If you are unable to watch the webinar live, you can speak to the study team to ensure that your questions are answered.

## **What will be required from me if I take part in the study?**

We ask that participants are able to commit to a year-long digital behaviour change programme with the aim of losing weight, improving diabetes control and in some cases, putting diabetes into remission.

The three dietary interventions that you can choose from are:

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### 1. Total Diet Replacement

This is a diet whereby you consume four meal replacement products per day for 12 weeks in place of food. Food is then slowly reintroduced and you are coached to form new, healthy habits to sustain your weight loss in the long term. A total diet replacement, or TDR, has shown to be the most effective method to lose a significant amount of weight safely and has been shown to put the diabetes of many people into remission.

### 2. Low-carbohydrate diet

A low-carbohydrate diet is another effective diet for those with type 2 diabetes. Carbohydrate breaks down into sugar and raises blood sugar levels, and high blood sugar levels are associated with diabetes. Therefore lowering carbohydrate intake, by reducing intake of foods such as bread, potatoes, rice, pasta and sugary foods, can improve blood sugar levels as well as offering weight loss. A low-carbohydrate diet can offer diabetes remission in some people.

### 3. 5:2 Diet

The 5:2 diet is an example of intermittent fasting. When following this diet, your calorie intake is significantly reduced on two days of the week, to 500 calories per day for women and 600 calories for men, whilst eating healthily on the other five days of the week. This dietary intervention is popular with some people, can promote significant weight loss and may offer diabetes remission in some people.

For you to take part in the study, we ask that you fill in a short questionnaire about your diabetes when you start the programme, and 1 and 2 years after you start. This questionnaire will help the dietitian to support you, and will help understanding of the impact of the programme. This questionnaire will take two to three minutes of your time.

You will also be invited to fill in short surveys about your experience of the programme, 16 weeks after the start, and again after 1 year. These surveys will be anonymous, and your responses will be sent only to the organisation evaluating the programme; they will not be shared with those providing your care. You do not have to complete these surveys, and your care will not be affected by how you respond. These surveys will take two to three minutes of your time.

A small number of patients will also be invited to take part in telephone interviews about the programme. Participation in these interviews will be voluntary, and will not affect your care in any way. You will be asked in the surveys if you are interested in taking part in these interviews, and invited to provide contact details if you are willing to be contacted for a possible interview. More

information about the interviews will be provided to those who express an interest, and you will be asked for consent before the interviews take place.

So we can understand the effectiveness of the programme, we ask that your GP sends us information about your diabetes, including weight, HbA1c, cholesterol, blood pressure and medications at the beginning of the programme and at 6, 12 and 24 months so we will require you to visit your GP for these tests.

## **How would the programme be delivered?**

Depending on your GP practice, some patients will receive their support in a group session and some will receive individual 1 to 1 support. You have been allocated to the **1 to 1** programme. You will receive individualised support from a Diabetes Specialist Dietitian.

For the first 16 weeks, you will receive support weekly through the Oviva smartphone app, or fortnightly telephone or video calls, and after that point you will receive monthly telephone or video calls until the end of the year-long programme. The sessions will be used to support you to make diet and lifestyle changes to help you reach your goals.

## **What are the benefits of taking part?**

By taking part, you will receive support to reach your health goals. The aim of the programme is to help people lose weight,, improve quality of life, and reduce medications and reverse type 2 diabetes in some people.

By taking part, you will also help us collect valuable information which will be used to improve services for patients in the future.

## **What are the potential disadvantages of taking part?**

We do not consider there to be any serious disadvantages of taking part in the study but we request your time and commitment. We ask you to commit to the year long programme, attend your GP appointments when required to have your relevant tests, and to fill out the surveys at the required time points.

## **Will I get paid for participating?**

No, you will not be paid for participating in the study. If you choose to follow the TDR, all products will be funded for you.

All participants will be given a set of digital scales which they will be encouraged to use throughout the programme and can keep after. If you leave the study early we will ask that these are returned.

## **Do I have to take part?**

No, you do not have to take part. Even if you choose to take part, and then change your mind, you are free to do so.

## **How will information be collected and stored?**

Oviva are responsible for delivering the Transform Diabetes Study, but will not be carrying out the evaluation. This will be done by Insight Health Improvement, the evaluation partner appointed by the NHS. Anonymous data about the people who take part will be provided to the evaluation partner by your GP and Oviva. This will include demographic data (year of birth, sex, ethnicity), clinical information about your diabetes and the care you receive, information about your participation in the programme.

Whilst you are taking part in the study with Oviva, your clinical information will be stored in a secure digital healthcare system in line with Oviva's healthcare practices. All information about you will be kept safe and secure at all times.

## **What will happen to the results of the study?**

Results will be analysed and will be published 6-12 months following completion of the study with the aim of submitting to a peer-reviewed journal. No information that could identify any participant will be included in the report. The report will be available on the Oviva website.

## **Who should I contact for further information?**

Lucy Jones, VP Clinical (Oviva) - [lucy.jones43@nhs.net](mailto:lucy.jones43@nhs.net)

Thank you.