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The 'DR-EAM' study – (Type 2) Diabetes weight Reduction - Evaluation of App coaching Model

Participant Information Sheet

About this study

The number of people living with type 2 diabetes in the UK is growing rapidly. The majority of people will require medications to manage their type 2 diabetes, and can also have other health problems such as high blood pressure, pain or depression. Often these conditions are treated with further medications. This can be upsetting, as people can feel their health is out of control, and they can have issues such as the hassle of organising daily medications. The cost of treating type 2 diabetes for the NHS is very high.

Recently a big study showed that weight loss delivered with intensive one-to-one support can help people with type 2 diabetes come off their medications for blood pressure and blood sugar. Participants also achieved healthy blood sugar levels. Such benefits are wonderful for patients and save significant NHS resources.

Unfortunately intensive programmes like this are expensive.

Oviva™ has developed "Diabetes 800" which can be delivered remotely, instead of face-to-face, and is already delivered in the UK. Not only is this lower cost, it also offers more flexibility to the individual patient.

In this project we plan to study the effect of Diabetes 800 on weight loss, blood sugar control and medication use in 250 people with type 2 diabetes.

We then plan to use the information we get from this project to work out exactly how much money Diabetes 800 could save the NHS if it were rolled out across the country. We hope that this work will provide people with type 2 diabetes more options to manage and improve their health.

What do you need from me if I decide to take part in the study?

You will agree to take part in the Diabetes 800 programme which is remotely delivered (via an app and face-to-face video calls) to help you change your diet and lose weight. Details of the programme are found below.

To enable us to evaluate the programme we are asking for the following:

1. For you to complete a short questionnaire that Oviva will send you, on why you took part in the study and what you think of it.
2. If you stop using the OD800 programme for any reason we will ask you to complete a short questionnaire (two questions) on why you stopped using the programme, and any suggestions you have to improve it.

3. We are asking for your **permission** to use your anonymized data (weight, HbA1c (a measure of your blood sugars), cholesterol, and change in medications), physical activity and quality of life, as part of your involvement in the OD800 programme, for us to know whether the programme has been successful.

More information on how we will use your data is below.

What is the Diabetes 800 programme:

Diabetes-800 is a digital, remote behaviour change intervention, which provides personal 1 to 1 support and expert advice delivered either over the phone or via the Oviva App.. The programme is 12 months in duration inclusive of a 12 week low-calorie diet (approximately 800 calories per day), a four week food reintroduction phase and nine months of behaviour change support from a registered dietitian, with additional support from a diabetes specialist nurse where required.

- The programme is 1 year long, but we will collect follow-up measurements such as blood sugar and blood pressure at 24 months.. So you will be in the study for 2 years.
- You will begin with a 45 minute initial consultation with your dietitian who will support you throughout the whole programme.
- You will then start on a meal replacement programme for 12 weeks when you will consume only four meal replacement products per day which will provide all of your nutrition. This is known as a total diet replacement, a diet that has shown to be very effective in people with type 2 diabetes for achieving weight loss and improvement in blood sugar levels
- You will then move onto a four-week food reintroduction phase when you will go back onto a food-based diet but you will gradually increase your calorie intake as guided by your dietitian. During this phase you will continue to have regular contact with your dietitian for close guidance and support.
- You will then move into the 'Sustain' phase with monthly support from your dietitian to help you maintain the changes you have made and build long lasting habits to keep the weight off in the long-term. The aim for this phase may be to maintain the weight you have already lost or it might be to achieve further weight loss if you feel you still have more weight you would like to lose.

What will be asked of me during the 2 year study period?

The programme is delivered remotely so the programme itself, and all your appointments with the Oviva healthcare professionals can be done from your home, and at a convenient time to you. Your weight and physical activity can be measured at home with the equipment we give you. We will send you a questionnaire that needs to be completed electronically and you will need to visit your GP for measurement of your blood sugar, cholesterol and blood pressure. However, part of usual NHS care is frequent visits to the GP for these measures, especially for blood sugar, so these will be timed to fit in with your usual clinical schedule. Your GP will then send Oviva your blood test results and any changes in medications.

Additional activity for the evaluation includes:

HbA1c at 24 months
Cholesterol at Start of study, 12 & 24 months
Blood pressure 12 & 24 months

Schedule	***Start of study***	***6 months***	***12 months***	***24 months***
HbA1c (blood sugar)	x (within 3 months of referral)	x	x	**x**
Cholesterol	**x**		**x**	**x**
Blood pressure	x (within 3 months of referral)		**x**	**x**

What are the possible disadvantages and risks of taking part?

We do not consider there to be any serious disadvantage if you take part in this study. The only disadvantage would be the time it takes (5 to 10 minutes) to complete a short questionnaire about your experiences with the Diabetes-800 programme.

Will I get paid for participating?

We regret that we cannot provide reimbursement or payment for taking part, though you will receive the Diabetes 800 programme, the Oviva app, a device which measures your steps (a Fitbit), and electronic scales for free.

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 and do not need to give a reason. This will not affect your care. If you choose, you can still participate in the Oviva 800 programme but decide not to allow us to access or use your data.

What if there is a problem?

Any complaint about the way you have been dealt with during the study or any possible harm you might suffer will be addressed. The detailed information on this is given below.

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What information will be collected and who will have access to the information collected?

Oviva are responsible for delivering the OD800 programme, but will not be carrying out the evaluation. They will collect some data to send to UoW and IHI who will be responsible for the evaluation, but your identity will not be shared with either evaluator.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

We will keep all information about you safe and secure.

Some of your information will be stored in our secure storage in Switzerland. They must follow our rules about keeping your information safe.

How will we use information about you?

We will need to use information from you and your GP for this research project.

This information will include:

- name and contact details
- NHS number
- weight
- height
- gender
- age
- HbA1c
- blood pressure
- Medications you are taking

People will use this information to do the research or to check your records to make sure that the research is being done properly.

As part of the OD800 programme, we will also send you an eligibility survey and a client satisfaction and health survey. You will be asked to complete these surveys.

At the end of the study, Oviva will send the data collected to researchers at the University of Westminster and Insight Health Improvement who are health economists.

Prior to sending the data, Oviva will make sure your data is anonymised - this means that your name, date of birth, NHS number, address or any identifiable information is removed from the database before sending. The email will be sent via encrypted mail; and will be held on secure servers at the University of Westminster.

The information will only be used for the purpose of research, and cannot be used to contact you. It will not be used to make decisions about future services available to you.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

What will happen to the results of the research study?

The results are likely to be published 6-12 months following the study. The information of the study will be put on the Oviva, UoW and IHI websites. Your confidentiality will be ensured at all times and you will not be identified in any publication. At the end of the study, the results of the study can be made available to you.

Who is the sponsor and data controller for this research?

The University of Westminster is the sponsor for this study. The University of Westminster will be using anonymised information from you in order to carry out the analysis.

Insight Health Improvement (IHI) is an independent evaluator. They will be performing the Health economic analysis, to work out exactly how much money Diabetes 800 could save the NHS if it were rolled out across the country. They will be using anonymised information from both participants in the study, as well as a control group who are receiving routine NHS care, to carry out the analysis.

Oviva, a provider of NHS services, will be providing your care during this study. Oviva is responsible for looking after your information and using it properly.

Your rights to access, change or move your information are limited, as Oviva needs to manage your information in specific ways in order for their programme to be reliable and accurate. If you withdraw from the study, Oviva will keep the information about you that has already been obtained but it will not be used in any analysis by the University of Westminster or Insight Health Improvement.

What are your choices about how your information is used?

You can stop participating in the study at any time, without giving a reason, but Oviva will keep information about you that they already have. However, if you choose to withdraw from the study Oviva will not share this information with the University of Westminster or Insight Health Improvement.

Where can you find out more about how your information is used?

You can find out more about how we use your information at:

- www.hra.nhs.uk/information-about-patients/

or

- Contact the **Information Compliance Manager** at the University of Westminster: dpa@westminster.ac.uk

What if something goes wrong?

University of Westminster holds insurance policies which apply to this study. If you experience serious and enduring harm or injury as a result of taking part in this study, you may be eligible to claim compensation without having to prove that University of Westminster is at fault. This does not affect your legal rights to seek compensation.

If you are harmed due to someone's negligence, then you may have grounds for a legal action. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been treated during the course of this study then you should immediately inform Dr Nicola Guess 07951 252395.

What can I do if I have any complaints or concerns?

If you have a concern about any aspect of this study, you can contact:

Dr Nicola Guess, 4th floor, Life Sciences, 101 New Cavendish St, Fitzrovia, London W1W 6XH.

Email: Guessn@westminster.ac.uk

Tel: 07951 252395.

Will my taking part in this study be kept confidential?

All information that is collected about you during the course of the research will be kept strictly confidential.

Who is funding this research?

Innovate UK is funding this research. Innovate UK is part of UK Research and Innovation, a non-departmental public body funded by a grant-in-aid from the UK government. For more information, visit the UK Research and Innovation website.

Has this study received ethical approval?

This study has received ethical approval from NHS committee on 03/12/2020

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Who should I contact for further information relating to the research?

Dr Nicola Guess, University of Westminster. Email: Guessn@westminster.ac.uk

Rosemary Huntriss, Clinical Research lead at Oviva. Email: contact_uk@oviva.com