MRC | Epidemiology Unit

UNIVERSITY OF CAMBRIDGE

Participant Information Sheet
Glucose Lowering through Weight management Study

GLOW

We invite you to take part in a research study

- Before you decide whether or not you wish to take part please take the time to read the following information carefully, it explains why the research is being done and what it will involve. Discuss it with friends, relatives and your GP/practice nurse if you wish.
- You are free to decide whether or not to take part in this research. If you choose not to take part, this will not affect the care you get from your GP.
- Ask us if there is anything that is not clear or if you would like more information.
- Thank you for reading this information sheet.

Key information

- We want to compare two diabetes education programmes and see which is better at helping people with newly diagnosed diabetes.
- Half of the people in the study will be offered a diabetes education programme called "DESMOND".
- The other half will be offered a diabetes education and weight management programme called 'Live Well With Diabetes'.
- We will monitor your health over the next year. You can stop taking part in the study at any time, without giving a reason.
- Your confidentiality will be maintained at all times. All information collected about you will be stored securely by the University of Cambridge.

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How to contact us

If you have any questions about this study please talk to:

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Tel: 0800 783 4611
Email: GLOW.study@mrc-epid.cam.ac.uk

About this study

People with type 2 diabetes are at increased risk of developing other health problems such as heart disease and stroke. We are doing this study to find out the best way to help people with type 2 diabetes to lower their blood glucose, improve their health and reduce their risk of developing other health problems.

What treatments are we looking at?

The GLoW trial will evaluate two programmes which have been shown to support people with type 2 diabetes to improve their diet and physical activity and improve their health. The first programme is a diabetes education programme called DESMOND, which involves attending a one day group diabetes education session in person. The second is a diabetes education and weight management programme called "Live Well With Diabetes". This involves diabetes education from a registered dietitian over the phone and gives you access to weekly Weight Watchers meetings (free of charge).

What do we hope to find out?

We will compare the two programmes and see which one has the best impact on health and well-being and which one offers the best value for money for the NHS.

How do we find out whether the new programme works?

The only way to tell which programme is better, is to run a research study (called a trial) to compare the two programmes. We do this by randomly allocating people into one of two groups: one group receives DESMOND; and one group receives Live Well With Diabetes. Measurements are taken and compared over time.

How is it decided who gets the new programme?

A computer programme will choose which programme you get – this is called 'randomisation'. This is a bit like tossing a coin. It means you have an equal chance of receiving each programme.

The rest of this leaflet explains how you might be involved in our research study.

2 Why am I being asked to take part?

You are being invited to take part because you have been diagnosed with type 2 diabetes in the past 3 years and your last recorded Body Mass Index (BMI) was over 25 kg/m^2. We are inviting 576 people in the area to take part.

Do I have to take part?

No, it is up to you to decide whether or not to take part in the study. You are free to withdraw at any time without giving a reason. This will not affect the standard or type of care you receive.

3 What will happen and how will I be involved?

If you are interested in taking part in the study, you will need to contact us by email or telephone. Contact details can be found on the front and back pages of this leaflet.

We will explain the study in more depth. We will then ask you some questions to check that you are able to take part. This will include questions about your current weight and whether you've taken part in any diabetes education programmes before.

If you are eligible, we will book you in for an appointment with a nurse at your GP practice.

Clinic Health Checks

We will invite you to go to your local GP practice and you will meet with a trained nurse, healthcare assistant, or research assistant. They will explain the study process and answer any questions you may have. If you agree to take part, you will be asked to sign a consent form.

There are 3 clinic visits to attend – one at the start of the study, one 6 months later, and another at 12 months. This helps us to see if your health has changed over time and if the programme has helped you or not.

Each study visit will take approximately 30 minutes. The following measurements will be taken:

- Height, weight, body fat percentage
- Blood pressure
- Small blood sample (with your permission)

The blood sample is equivalent to just under 3 teaspoons full. It is used to look at the levels of sugars and fats in your blood, and markers of fruit and vegetable intake.

The results collected at the clinic health checks will be sent to you and with your permission, your GP.

At home

After each clinic visit, you will be asked to complete a short questionnaire at home (on paper or online). You will also be asked to complete an online diet questionnaire. You will be sent a waterproof watch-like physical activity monitor to wear, which will measure your movement over 7 days and nights.

The programmes

Group 1: If you are allocated to the diabetes education group you will be asked to attend a diabetes education programme (DESMOND) that is currently offered in the NHS in your region. It is delivered in local community venues by trained health care professionals in small groups of up to 10 people. The education session will take about 6 hours in total and is usually offered as a one day session or two half-day sessions.

Group 2: The Live Well with Diabetes programme is delivered by a registered dietitian over the phone in two one-to-one phone calls (each lasting about 45mins). You will also be asked to attend weekly Weight Watchers meetings (free of charge) for 6 months. Each meeting lasts 30-40 minutes. You will be able to choose from a range of times, days and community locations. During this time you will also be able to access Weight Watchers digital tools, including the app, and you will be able to contact the dietitian or the Weight Watchers coach when you need support.

Taking part in this study will not limit the usual care provided by your GP. You will still be able to receive other treatment from your GP during the study. After the study ends you will return back to standard care.

Your health records

With your permission we would follow up on your health after the study has finished to assess the longer term effects of the two programmes.

With the help of your GP, we will collect information from your medical notes about your health and health care use. If you are unable to attend the visit (and with your consent) we will also collect details on your most recent weight, blood pressure and blood test results.

We will also use national data sources that hold data on your health, such as hospital attendance and whether you develop any serious health conditions such as cancer or heart disease. We will use these data sources to find out information about your health and to see what health and social care resources you have used.

We also request and receive recent address and GP information from NHS Digital to enable us to keep in touch as people move over the years.

Interviews

Some participants will also be asked to take part in a discussion with one of the study teams' researchers about their experiences after their treatment programme has ended. The interviews will be digitally recorded and we will approach you separately about this

4 Possible benefits and disadvantages of taking part

Benefits of taking part

The information you provide in this study will help our research into the prevention and treatment of obesity and type 2 diabetes. You will be part of a unique study that may be helpful in promoting a positive change in the current system utilised in the UK for diabetes education referral. You will receive one of two treatments which may help to improve your health. If you are allocated to the Live Well with Diabetes programme, you will receive a free weight management programme that is not currently offered by the NHS in your area. You will receive additional health checks at your GP practice, and we will send you the results of these directly.

As a thank you for taking part, you will receive a £10 high street voucher for attending the first two visits and a £30 high street voucher for the 12 month visit. We will also reimburse the cost of your travel to and from your GP practice.

Disadvantages or risks of taking part

Other than the time it takes you to attend the visit and complete the questionnaires, there should be very little risk or disadvantage to taking part. When taking a blood sample there is a small risk of bruising, inflammation and fainting. Research staff are trained and experienced in taking blood samples in a way that minimises any discomfort.

5 If you have any questions or concerns

Questions about the study

Contact the study team:
(Freephone) 0800 783 4611
Email: GLOW.study@mrc-epid.cam.ac.uk

If you have a formal complaint

Contact the University of Cambridge Clinical School Secretary:
Tel: 01223 333543
Email: SchoolSec@medschl.cam.ac.uk

Independent Advice

If you would like some independent information and advice about taking part in this study, please contact your local Patient and Advice Liaison Service (PALS):
https://www.nhs.uk/chq/pages/1082.aspx?CategoryID=68

6 How will my information be looked after?

What will happen to information about me that is collected during the study?

Information we collect during the study will be kept strictly confidential. With your consent, we will tell you and your GP the results of from your clinic health checks.

With your permission, information we collect will be stored anonymously at the MRC Epidemiology Unit, University of Cambridge. You will be assigned a unique code when you first take part in GLoW. This code will be used to label all data collected during the study and is used in place of personal information. Personal identifiable information, such as the contact details we use to

keep in touch with you, will be kept separate from any other data we collect. The database containing personal information is on a secured network drive on computers in the MRC Epidemiology Unit, University of Cambridge.

In order to conduct the study and ensure you receive the highest standards of care, we may need to share information between the University of Cambridge, the programme providers (DESMOND and Weight Watchers), and your GP practice. We will keep this data-sharing to the minimum necessary and all parties will adhere to the highest standards of data security and confidentiality.

To obtain data on your health, we may also share your information with NHS digital, the national provider of information and data for health and social care, the National Cancer Registry, the Healthcare Quality Improvement Partnership, and the Office of National Statistics. We will use a secure web portal to send some of your identifiable data (e.g name, date of birth, GP and address) to these organisations. They will use this information to find the data that we requested and send this data to us in a link-anonymised form so that we can combine it with the other data we have collected as part of this study. For more information on how we protect your data please see our website: http://www.mrc-epid.cam.ac.uk/research/studies/glow-glucose-lowering-weight-management/

Anonymised data may be used to support other research in the future and may be shared with other researchers, with appropriate credentials, including those overseas or in the commercial sector. This will be solely for the purposes of research.

The University of Cambridge and the Cambridgeshire and Peterborough Clinical Commissioning Group are co-sponsors for this study based in the United Kingdom. The University of Cambridge will be using information from you and your medical records in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. The University of Cambridge will keep identifiable information about you for 20 years after the study has finished and it will then be destroyed.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

You can find out more about how we use your information https://www.medschl.cam.ac.uk/research/privacy-notice-how-we-use-your-research-data/

What will happen to any samples I give?

Any samples that are collected during the study will be processed and stored by the MRC Epidemiology Unit. Your unique GLoW code will be used to label all samples collected during the study so none of your personal data is put on the blood tubes. With your agreement, we may store samples for up to 10 years and then they will be destroyed. With your consent, and with the appropriate research ethics approval, retained samples and linked data may be used for future research (which may include collaborations with academic parties and the commercial sector both within and outside the UK).

What will happen to the results of the study?

When the study is completed, the results will be presented at scientific meetings and published in scientific journals. If published, your identity and personal details will be kept confidential. No

information that could identify you, like your name, will be published in any report about this study. We will also continue to provide you with a summary of our findings from the study through our newsletters.

Who is organising and funding the study?

This study is organised by the MRC Epidemiology Unit, part of the University of Cambridge.

The study is funded by the National Institute for Health Research (NIHR). The study is co-sponsored by the University of Cambridge and NHS Cambridgeshire and Peterborough CCG.

Who has reviewed the study?

The Study has been reviewed and approved by the Health Research Authority (HRA) UK, and the East of Scotland Research Ethics Service REC (REC Ref: 18/ES/0048).

Occasionally our studies may be monitored by our Sponsors. This is to ensure our research is conducted soundly and in the best interests of the participants. Your research records may be made available for this purpose to inspectors from the University of Cambridge, and NHS Cambridgeshire and Peterborough CCG.

It has also been reviewed by the NHS National Institute of Health Research, who awarded the funding for this study.

7 Contact for further information

If you would like to take part in the GLoW study, please call or email the study team to arrange an appointment.

Study Coordinator

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Chief Investigators

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Senior Investigator Scientist
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Prof Simon Griffin
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Thank you for taking the time to consider taking part in this study.