

Healthy Eating & Active Lifestyles for Diabetes - Research Study

## Participant Information Leaflet

**Study Lead: Professor Louise Goff, University of Leicester**

### INTRODUCTION

You are being invited to take part in a research study. Before you decide whether or not to take part, it is important that you understand why the research is being done and what it will involve. Please take time to read this information leaflet carefully and discuss it with others if you wish. That decision will not affect the care you receive in anyway. If there is any part of this information leaflet that you do not understand, or require further information about, please contact us and we will be happy to answer any questions you have. Our contact details are on the back page.

### ABOUT THIS RESEARCH STUDY

Healthy Eating and Active Lifestyles for Diabetes (HEAL-D) is a diabetes information and support programme for adults of black African and black Caribbean heritage living with type 2 diabetes, to help them manage their condition. The programme has been developed in partnership with African and Caribbean communities. It is based on guidelines to support type 2 diabetes management but is culturally suited to meet the needs of people of black African and black Caribbean heritage. For example, it contains information about how to make healthy choices for traditional meals in terms of food preparation, portion control, etc. The research study is open to participants based in London, Birmingham and Manchester.

### WHY ARE WE DOING THIS RESEARCH STUDY?

People of black African and black Caribbean descent are 2-4 times more likely to develop type 2 diabetes than other ethnic groups. Diabetes information and support programmes that are suited to cultural habits and preferences may help people better manage their diabetes and reduce inequalities like this. This research study will compare the benefits and the cost of the HEAL-D programme against current diabetes education programmes. If HEAL-D is shown to be beneficial and affordable for the NHS, we hope the HEAL-D programme will be made more widely available to black African and black Caribbean people living with type 2 diabetes in the UK. No individual or organisation will gain financially from completing this research.

### WHY HAVE YOU BEEN INVITED TO TAKE PART?

You have been invited to take part because you have type 2 diabetes and are an adult of black African or black Caribbean heritage. This study is not suitable for people with additional health conditions that require specialist medical treatment or dietary advice, such as advanced kidney disease, or for people who are pregnant or need translation services. You may also be unable to participate if you are taking part in other research studies.

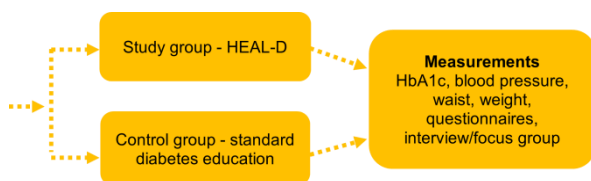
### DO YOU HAVE TO TAKE PART?

No, taking part in this study is voluntary. If you don't want to take part, this will not affect any ongoing care that you receive. If you do decide to take part but later

change your mind, you are free to withdraw at any time by contacting the research team using the information provided at the end of this document.

### WHAT IS INVOLVED?

If you would like to take part, all the details will be explained to you by one of the research team. You will be able to ask questions and if you decide you would like to take part, then you will be asked to give your written consent. You will be allocated to attend either the 'study group' or the 'control group'. This allocation is done randomly by a computer and is not under the control of the research team.



### The study group:

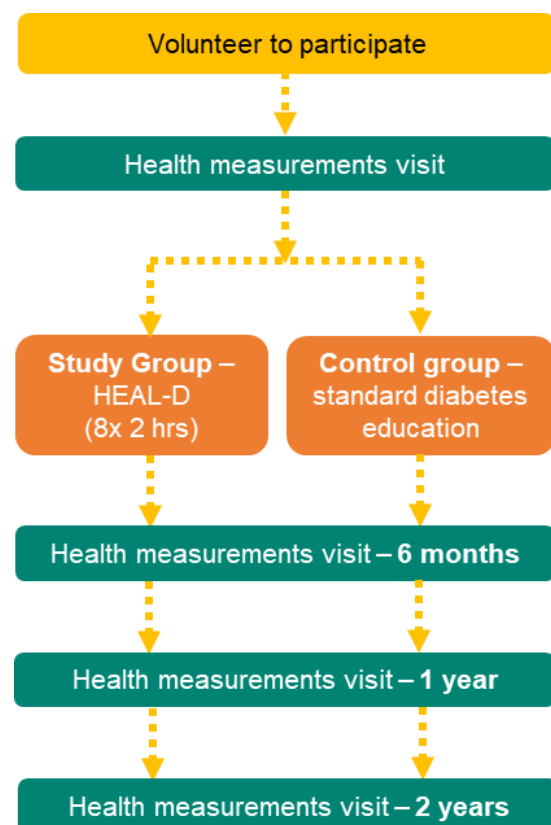
If you are allocated to the 'study group' you will be offered the HEAL-D programme. This includes 7 sessions that will take place every 2 weeks, followed by an 8<sup>th</sup> session 6 months later. Each session lasts 2 hours. These sessions will be available in a location near your home, or online using video calls. In-person sessions will take place in community spaces, like a church hall or community centre. Each session will include information about diet and physical activity to help you manage type 2 diabetes. Some of these sessions will involve group physical activity sessions (activities may include a walking group, gym training or a dance class, and are for all abilities). The physical activity classes will be run by a qualified health professional. They will ensure that you are safe to take part in the activities and

will make sure activities are suited to your needs and ability.

### The control group:

If you are allocated to the 'control group' you will be offered the diabetes education programme that is currently delivered in your local area. You will be offered a choice of attending this programme in person or online, using video calls. You will not take part in the HEAL-D sessions. We have this group so that we can compare the difference between the people attending HEAL-D and those attending other education programmes.

### RESEARCH STUDY TIMELINE



### MEASUREMENTS

Both groups will require you to undergo some health measurements at the start of the research study and then again 6

months, 1 year and 2 years after starting the study. These measurements will be taken in local appointments with the research team, for example, at a local GP practice or hospital. We need these measurements so we can tell if the programme works. The measurements that will be taken are:

**Blood test:** 5 mL blood (about a teaspoon) will be collected from your arm to measure HbA1c (a marker of diabetes management) and your cholesterol level. You will have had these tests done before at your doctors. Your blood samples will be analysed at a local hospital and then destroyed.

**Measurements:** waist circumference, body weight, height, blood pressure.

In addition, you will be asked to **complete a questionnaire booklet** (one of the research team can help you complete this). The questionnaire will ask you about yourself, what you think about living with diabetes, your attitude towards health and lifestyle and your physical activity habits.

**Physical activity monitor:** you will be provided with an activity watch to wear on your wrist or arm for 10 days after each visit. This device will measure your physical activity level.

During the study you may be asked to take part in a telephone **interview** by a member of the research team, and/or the chance to join a group **workshop** with other study participants and staff who delivered the HEAL-D programme. Both will ask you to discuss what you liked and didn't like about the programme.

Interviews will be audio recorded and this recording will be pseudonymised (coded)

and sent to an external company (transcription service) who will type up the audio recordings into a script (called a 'transcript'). During this process they will remove any information that identifies you. A confidentiality agreement will be in place prior to using these services, and they will not be provided with any identifiable data. Once the transcripts have been used for analysis, the audio recordings will be permanently deleted. Notes on the content of discussions will be taken by the research team throughout workshops. These notes will not contain identifiable information.

### WILL I BE PAID FOR TAKING PART?

You will receive reimbursements for your time, £200 over 2 years (£50 for each measurements visit you attend), plus travel expenses (up to £10 per-visit, plus parking). You will also receive £40 if you participate in an additional workshop and £25 for an additional interview.

### WHAT ARE THE BENEFITS OF TAKING PART?

If you chose to take part, you may help improve healthcare in your community. The results of this research study will be shared with you and your community and may improve NHS treatment for people of black African or black Caribbean heritage.

During the study you will personally receive regular health measurements, as well as diabetes information and support. This can help you manage your diabetes and improve your health and wellbeing.

### WHAT ARE THE DISADVANTAGES OR RISKS OF TAKING PART?

If you are allocated to the HEAL-D programme, this involves at least 16

hours of time commitment over 6 months. If you are allocated the current diabetes education programme in your area, this will involve a time commitment that varies depending on which programme is offered in your area. You will also attend 4 measurements visits over 2 years.

During the screening or assessment visits, it is possible that previously unknown conditions may be revealed which you may want support with. We will let both you, and your GP know about these findings, and either request that your GP makes the appropriate referrals for investigation, or where required, make direct referral into existing specialist services ourselves.

Blood tests can be uncomfortable, but these will be performed by professional staff, with care taken to minimise any discomfort. Your results will be shared with your GP to help inform your usual care.

### WHAT IF SOMETHING GOES WRONG?

It is very unlikely that you would be harmed by taking part in this type of research study. If you wish to complain or have any concerns about the way you have been approached or treated in connection with the study, you should ask to speak to the HEAL-D Trial Coordinator on 07825754785 who will do their best to answer your questions. If you remain unhappy and wish to address your concerns or complaints on a formal basis, you may wish to contact the hospital's Patient Information and Liaison Service (PILS). Contact details for the research team and PILS office are: (email) TBC and (telephone) TBC.

In the event that something does go wrong and you are harmed during the research and this is due to someone's negligence then you may have grounds for a legal action for compensation against University of Leicester but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you (if appropriate).

### WILL YOUR PARTICIPATION BE KEPT CONFIDENTIAL?

While you are taking part in the study, your contact details will be made available to the research team so they can contact you to arrange the details of your research appointments. On the consent form, you can also choose to be informed about the results of the study. If you consent for this to happen, we will store your contact details securely, separately from your data and clinical information, and we will only use them for the purposes you have chosen.

Your data may be accessed by authorised individuals from the University of Leicester and regulatory authorities for monitoring and audit purposes. We have a duty of confidentiality to you as a research participant and we will do our best to meet this duty.

Your contact details will be destroyed once they have been used for the purpose that you have agreed to, unless you give permission for them to be stored for longer. The study is taking place for 4 years. Coded research data will be stored for 6 years after the study has finished. If you give permission, we may access your health records (e.g. using NHS Digital) or contact your GP to find out information about your health



status as it relates to this study for up to 6 years after the study has finished.

We will inform your GP of your participation in this study and if any previously unknown conditions are revealed because of your participation in this study.

### HOW WILL WE USE YOUR INFORMATION?

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

This information will include your:

- Name
- Contact details
- NHS number
- Age

People will use this information to do the research or to check your records to make sure that the research is being done properly. 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. 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 ARE YOUR CHOICES ABOUT HOW YOUR INFORMATION IS USED?

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have. We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

### WHERE CAN YOU FIND OUT MORE ABOUT HOW YOUR INFORMATION IS USED?

- at [www.hra.nhs.uk/information-about-patients/](http://www.hra.nhs.uk/information-about-patients/)
- on the following website: [www.le.ac.uk/patient-gdpr-guidance](http://www.le.ac.uk/patient-gdpr-guidance)
- by asking one of the research team
- by contacting us via the e-mail address or phone number at the end of this sheet
- by contacting the University's Data Protection Officer via email on [dpo@le.ac.uk](mailto:dpo@le.ac.uk)

### WHAT WILL HAPPEN TO THE RESULTS OF THE RESEARCH STUDY?

We will share the research findings with healthcare professionals, NHS managers, charities and other organisations who support people living with type 2 diabetes so they can improve the care and support that they provide. If HEAL-D is found to be beneficial, we hope it will be made widely available in the NHS for African and Caribbean communities. We expect the results of the study to be published in several research papers and conference presentations. We will also share our progress and findings in regular participant newsletters and send you a copy of the final results if you want us to.

### WHAT SHOULD YOU DO IF YOU WANT TO TAKE PART?

If you want to talk to someone about the research study or you want to take part, you should contact the research team using the details at the end of this leaflet.

## WHO IS CONDUCTING THE RESEARCH?

The study is being led by researchers based in the Diabetes Research Centre at the University of Leicester. There are also researchers based at universities and NHS organisations in London, Birmingham and Manchester, who will be responsible for running the study in those areas. All of these researchers make up the research team. The organisations include Guy's and St Thomas NHS Foundation Trust, King's College London, Queen Mary University of London, St George's University of London, University College London, The University of Manchester, and University of Warwick.

## WHO IS FUNDING THE RESEARCH?

This research study is Sponsored by the University of Leicester. The project is funded by the National Institute for Health Research. No individual or organisation will gain financially from completing this research.

## WHO HAS REVIEWED THE RESEARCH STUDY?

This research was approved by the East Midlands - Leicester South Research Ethics Committee (reference: 24/EM/0079). Approval means that the committee is satisfied that your rights will be respected, that any risks have been reduced to a minimum and balanced against possible benefits and that you have been given sufficient information on which to make an informed decision. The study has also been reviewed by the University of Leicester.

Thank you for reading this leaflet and considering taking part in our research study.

## Find out more?

Website: [www.heal-d.org](http://www.heal-d.org)

Email: [HEAL-D\\_Study@leicester.ac.uk](mailto:HEAL-D_Study@leicester.ac.uk)

Call: 07825754785

Or scan the QR code here:



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