Dietary approaches to the management of type 2 diabetes The DIAMOND Study

PARTICIPANT INFORMATION SHEET

- We'd like to invite you to take part in this research study.
- Before you decide, it is important that you understand why the research is being done and what it would involve for you.
- Please take time to read this information, and discuss it with others if you wish.
- If there is anything that is not clear, or if you would like more information, please ask us. Our contact details can be found at the end of this participant information sheet.

WHAT IS THE PURPOSE OF THE STUDY?

Type 2 diabetes is a condition in which a person's blood glucose levels (also known as 'blood sugar' levels) are too high. It affects 1 in 16 people in the UK. We know that what we eat affects our blood glucose levels. We want to study whether it is possible for GPs and practice nurses to support people with type 2 diabetes to change their diet so that they achieve remission from diabetes. Remission means a person has normal or near normal blood glucose and does not need medicines for diabetes. Being in remission will greatly improve your chances of avoiding long-term risks from diabetes to your eyes, kidneys, heart, and brain. It will lower blood pressure and reduce the need for blood pressure medication.

The study will compare a new programme of support from a nurse and GP to help you change your diet over 6 months with the current best dietary advice delivered at your GP practice. The programme of support is called DIAMOND, and will support you to make quite big changes to the amount and type of food you are eating for 12 weeks and the type of food you are eating thereafter. To support you to change your diet you will be seen at your GP practice six times over six months. We will measure how well the advice is delivered, how successful people are in following different advice, and the changes people see in their weight and blood glucose levels, over a 12 month period.

WHY HAVE I BEEN INVITED?

We are looking for people with type 2 diabetes diagnosed within the past six years to take part in this study, who would like to use diet to improve their diabetes control, lose weight, or improve their general health. Your GP has searched in their records to see who might be eligible to take part. Your medical records suggest that you may benefit from changing your diet in order to achieve remission from diabetes and improve your general health.

The University of Oxford did not have access to any of your personal or medical information as part of the invitation process. The University of Oxford collaborates with GP practices across the UK, of which your practice is one, who help to identify people who may be suitable and interested in taking part in research.

DO I HAVE TO TAKE PART?

No, it is up to you whether you take part or not. If you do decide to take part in the study you will be asked to sign a consent form at your first appointment. You are free to withdraw at any time without giving a reason. A decision to withdraw from the study will not affect the usual care you receive from your GP or practice nurse or other healthcare professional.

WHAT WILL HAPPEN IF I WANT TO TAKE PART?

If you are interested in taking part, a member of the research team will ask you questions to check if you may be suitable for the trial. If you are, then we will ask you to attend an appointment with one of the trial research nurses. The appointment will be at your GP practice and should not take longer than 30-45mins. We will ask you to sign a consent form agreeing to take part in the study, and the research nurse will complete questionnaires with you. The research nurse will also measure your blood pressure and take your blood to measure your HbA1c levels. You will also be asked to visit the GP practice after 6 months and 12 months to measure blood glucose levels. We will also ask you to monitor your blood pressure and blood glucose levels between these appointments at home.

Half the people who take part will be asked to continue with current best care for diabetes at the practice and half will be given the DIAMOND programme. You will not be able to choose which group you are in as this is decided randomly, like tossing a coin. If you are asked to be a part of the DIAMOND programme, in addition to your study visits at 6 months and 12 months, we will ask you to attend a structured diabetes programme six times over six months which will support you to change your diet. You will also be asked to stop your medicines for diabetes and high blood pressure. Taking these medicines while being a part of the DIAMOND programme could cause some problems like feeling dizzy or low blood glucose levels.

The NHS collects information about you and your diabetes care as part of the National Diabetes Audit. This is an NHS programme to improve the quality of care that the NHS gives to people with diabetes. We will ask you to agree to use your NHS number to collect information about your health through the National Diabetes Audit. This concerns measures of your blood sugar, blood pressure, and illnesses you could develop like heart disease, or problems with your eyes or kidneys. We will collect this information from the NHS every year to see whether the programme leads to benefits in the long-term or not.

Interview

A few people will be asked to take part in a longer conversation to understand how you felt about the DIAMOND programme and how it helped you or did not help you. A researcher at the University of Oxford will contact you and arrange this at a convenient time. This part of the trial is optional. If you are invited and decide to take part in this conversation, we will audio-record and transcribe the conversation.

WHAT SHOULD I CONSIDER?

If you decide to take part, you should not be planning to get pregnant or breastfeed in the next 12 months, and should be willing to attend six support sessions over six months and change your diet to improve your blood glucose level. To be able to take part in the study, we need to confirm that you do not have any medical conditions that might make the dietary advice we are giving unsuitable for you. The programme is not suitable if you are taking insulin as a treatment for your diabetes, having certain types of diabetes-related eye problems, or having developed a serious medical condition within the last 3 months (like a heart attack, stroke, cancer, or heart failure). When you speak to our study team, we will go through a list of questions with you to check the programme is suitable for you, and our research team can check any answers that you are not sure about with your GP.

If you agree to take part in the study, you would need to:

- Follow your allocated treatment to the best of your ability
- Allow us to collect three blood samples from you, depending which study group you are in
- Complete 3 questionnaires, which we will provide
- Attend appointments with your practice nurse, at your local practice. The maximum number of appointments you would be asked to attend would be 8 over a 26 week period, with one additional follow-up visit at 12 months.

When you have enrolled in the study, if you are due to book your next appointment but we haven't yet heard from you (or if you miss an appointment and don't manage to contact us beforehand to reschedule), we will attempt to contact you to remind you that you are due to book an appointment (by telephone, email or post, according to what contact information you have given us). We will aim to do this up to 3 times. If we haven't managed to contact you after this we will leave it to you to contact us if you still want to continue and book an appointment.

ARE THERE ANY POSSIBLE DISADVANTAGES OR RISKS FROM TAKING PART?

There are no known serious risks from the dietary advice that is being given in this study. However, sometimes when people change their diet they can become constipated –but this is easily prevented and treated, and if you take part in the study we will give you advice to help prevent this happening, or treat you if you do develop constipation.

If you are asked to follow the DIAMOND programme and you agree to do so, we will stop your medicines for diabetes and high blood pressure. We will ask you to monitor your blood glucose and your blood pressure to check that all is well and your GP may restart medications if not. If you take warfarin, changing your diet may change your INR level – so you should inform your local warfarin monitoring service, who may advise an additional blood test.

Most of the questionnaires we will use to ask about your feelings and your diet have been

previously used in many other studies and we do not expect these would cause you any distress.

As with any blood sample, there is possibility that you may develop some bruising around the area and some people occasionally faint while the sample is taken.

What are the possible benefits of taking part?

Everybody who takes part will receive at least two extra appointments with the practice nurse, and information about how diet can help in managing diabetes. The blood tests are also an additional health screening check. We will also share the results with you and your doctor who can arrange any further treatment you may need if a problem is detected. The knowledge gained in this study will help us know how best to help people with type 2 diabetes in the future and may mean people can achieve remission from diabetes.

Will I be reimbursed for taking part?

You will be offered a £20 voucher for each of the two follow-up appointments, at 6 and 12 months, as a way of reimbursing you for your time and any expenses in travelling to the appointment.

Will my General Practitioner/family doctor (GP) be informed of my participation?

Your GP will be notified of your participation and will receive the results of your blood tests throughout the study. Taking part in the study will not affect care you receive from your GP for any other unrelated conditions.

Will my taking part in the study be kept confidential?

Any information that is collected about you during the course of the research will be kept strictly confidential. We will use codes to avoid identifying you with your name.

Responsible members of the University of Oxford may be given access to data for monitoring and/or audit of the study to ensure that the research is complying with the appropriate regulations.

What will happen to the samples I give?

The blood samples will be analysed in your local hospital to measure your blood glucose, liver function, and cholesterol levels. These results will come back to your GP and your GP could decide to take action as part of your usual care. The hospital destroys your samples after analysis.

What will happen to my data?

We will follow the same standard procedures that the University of Oxford's Primary Care Clinical Trials Unit have set up to store all your information securely, including your contact

details. We will need your contact information to contact you at the time points mentioned above. Once the study is finished, we will anonymise all the data collected so that it is not possible to know that the data came from you, as you will only be identified by a code number.

UK Data protection regulation requires that we state the legal basis for processing information about you. In the case of research, this is 'a task in the public interest.' The University of Oxford (the sponsor for this study, based in the United Kingdom) is the data controller and is responsible for looking after your information and using it properly.

We will be using information from you, your medical records, NHS digital and other central NHS registries in order to undertake this study and will use the minimum personally-identifiable information possible. We will keep identifiable information about you for 20 years , in order to collect information through the National Diabetis Audit, after the study has finished. This excludes any research documents with personal information, such as consent forms, which will be held securely at the University of Oxford for 30 years after the end of the study. You will not have to do anything for us to collect this information.

You might be invited to take part in an interview or discussion group. If you take part in the discussion group, this will be audio-recorded, and then transcribed. The transcriptions will be anonymised as soon as possible, so that you are not identified in the transcript (except by a unique code number), and the original audio recording will then be deleted. The recordings will be transcribed either internally or by an approved external transcriber, with confidentiality and conduct contract in place with the University.

Data protection regulation provides you with control over your personal data and how it is used. When you agree to your information being used in research, however, some of those rights may be limited in order for the research to be reliable and accurate. Further information about your rights with respect to your personal data is available at https://compliance.web.ox.ac.uk/individual-rights

You can find out more about how we use your information by contacting diamond.trial@phc.ox.ac.uk.

WHAT WILL HAPPEN IF I DON'T WANT TO CARRY ON WITH THE STUDY?

Your participation is voluntary. If you decide you do not want to take part in the research at any point that is fine, and you can withdraw at any time without giving a reason. We will give you the opportunity to tell us the reason for withdrawing if you would like to. Your future medical care will not be affected.

We will use the data that has been collected up to the point at which you decide to withdraw from the study. This includes the data from the discussion if you have already taken part in this. We would continue to use this anonymised data after your withdrawal from the study.

What will happen to the results of this study?

The results of this study will help us to know how best to help people with diabetes achieve remission. The NHS already is developing different programmes to help people achieve remission and may use the DIAMOND programme as one of the ways to help people.

The study results will be presented at scientific meetings and published in a scientific journal. You will be not identified in the presentations and publications. We will send you a summary of the study results once the study has finished.

What if something unexpected is found?

Your blood tests will be sent to your GP for review, and he/she will be in touch if anything unexpected was found.

What if there is a problem?

The University of Oxford, as Sponsor, has appropriate insurance in place in the very unlikely event that you suffer any harm as a direct consequence of your participation in this study (including, for the avoidance of doubt, through the study-specific use of loaned blood pressure monitors, for example). NHS indemnity operates in respect of the clinical treatment which is provided.

If you wish to complain about any aspect of the way in which you have been approached or treated during the course of this study, you should contact the chief investigator, Prof Paul Aveyard on 01865 617860 or diamond.study@phc.ox.ac.uk ; or you may contact the University of Oxford Research Governance, Ethics and Assurance (RGEA) office on ctrg@admin.ox.ac.uk or 01865 616482

The Patient Advisory Liaison Service (PALS) is a confidential NHS service that can provide you with support for any complaints or queries you may have regarding the care you receive as an NHS patient. PALS is unable to provide information about this research study. If you wish to get in touch with the PALS team please contact them at PALS@ouh.nhs.uk.

How have patients and the public been involved in this study?

Members of the public helped to shape the ideas for this research, and to decide the questions that we are trying to answer. In designing this study we have taken into account patient opinions on the schedule of appointments that you will be asked to attend, and what information people want to have available to help them change their diet. One of our patient representatives has become a member of the study team and will continue to be involved throughout the study. Two members of the public will oversee the progress of the study and will have a prime role in ensuring the public interest always comes first.

WHO IS ORGANISING AND FUNDING THE STUDY?

The present study is funded by the National Institute for Health Research (NIHR) Health Technology Assessment Programme. The University of Oxford is responsible for the design, conduct and publication of results from this study. No personal information about you will be shared with the funder or included in any future publication.

WHO HAS REVIEWED THE STUDY?

All research in the NHS is reviewed by an independent group of people called the Research Ethics Committee, who protect your rights, safety, wellbeing and dignity. This study has been reviewed and given favourable opinion by East Midlands – Nottingham 2 Research Ethics Committee.

FURTHER INFORMATION AND CONTACT DETAILS:

If you want to discuss the study in more detail please contact us on:

Contact Name: Jadine Scragg
Tel: 01865 617131
Email: diamond.study@phc.ox.ac.uk

Thank you for taking the time to read this information sheet