PARTICIPANT INFORMATION SHEET

The effectiveness of a low-carbohydrate, low-energy diet with remote support for patients with type 2 diabetes in primary care on weight loss: a proof of concept (PoC) trial

We'd like to invite you to take part in this research study. Before you decide whether to take part, 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 – you can get in touch with us using the contact details below.

SUMMARY

We are looking for people with type 2 diabetes, who would be willing to make changes to their diet to lose weight and improve their diabetes, and are able to use a computer and access the internet

Half of the people who participate in this study will be allocated to the new programme called 'eDIAMOND', and the other half of participants will continue to receive their standard NHS diabetes care. eDIAMOND is a "remote" (ie, not in-person) version of an existing programme called DIAMOND. The purpose of this study is to determine whether DIAMOND can be delivered remotely.

In this study we want to see whether people with type 2 diabetes are able to change their diet over a 5 month period and lose weight, improving their diabetes and general health. Participants allocated to the 'eDIAMOND' programme will be supported by a health coach via phone and/or video calls, and will also have additional support via a website.

Our contact details

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WHAT IS THE PURPOSE OF THE STUDY?

We want to study whether the new eDIAMOND programme can help people with type 2 diabetes and who are overweight to lose weight and lower their blood glucose levels. This programme will support patients to make quite big changes to the amount and type of food they are eating for 12 weeks and then to settle into a way of eating that they can continue in the long-term to help keep their diabetes under control.

At present most people with type 2 diabetes receive support to manage their diabetes from their practice nurse. This usually includes advice on healthy eating and physical activity. Here we want to test whether more intensive advice is more effective. We also want to see whether it is helpful to have extra support from a health coach, via your phone or computer (such as phone or video calls, and text messages) rather than in person along with access to information and other resources on a website.

We will measure the changes people see in their weight, blood glucose levels, cholesterol and blood pressure over 5 months. We will also measure whether people are able to take fewer medications for their diabetes and blood pressure.

WHY HAVE I BEEN INVITED?

- We are looking for people with type 2 diabetes to take part in this study, who would like to use diet to improve their diabetes control, lose weight, or improve their general health. If this applies to you, please read on for further information.

- Your GP has searched in their records to see who might be eligible to take part. The University of Oxford did not have access to any of your personal or medical information as part of the invitation process. We collaborate 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.

The study will involve 60 patients with type 2 diabetes (30 will be allocated to eDIAMOND programme and 30 will be allocated to standard NHS care)

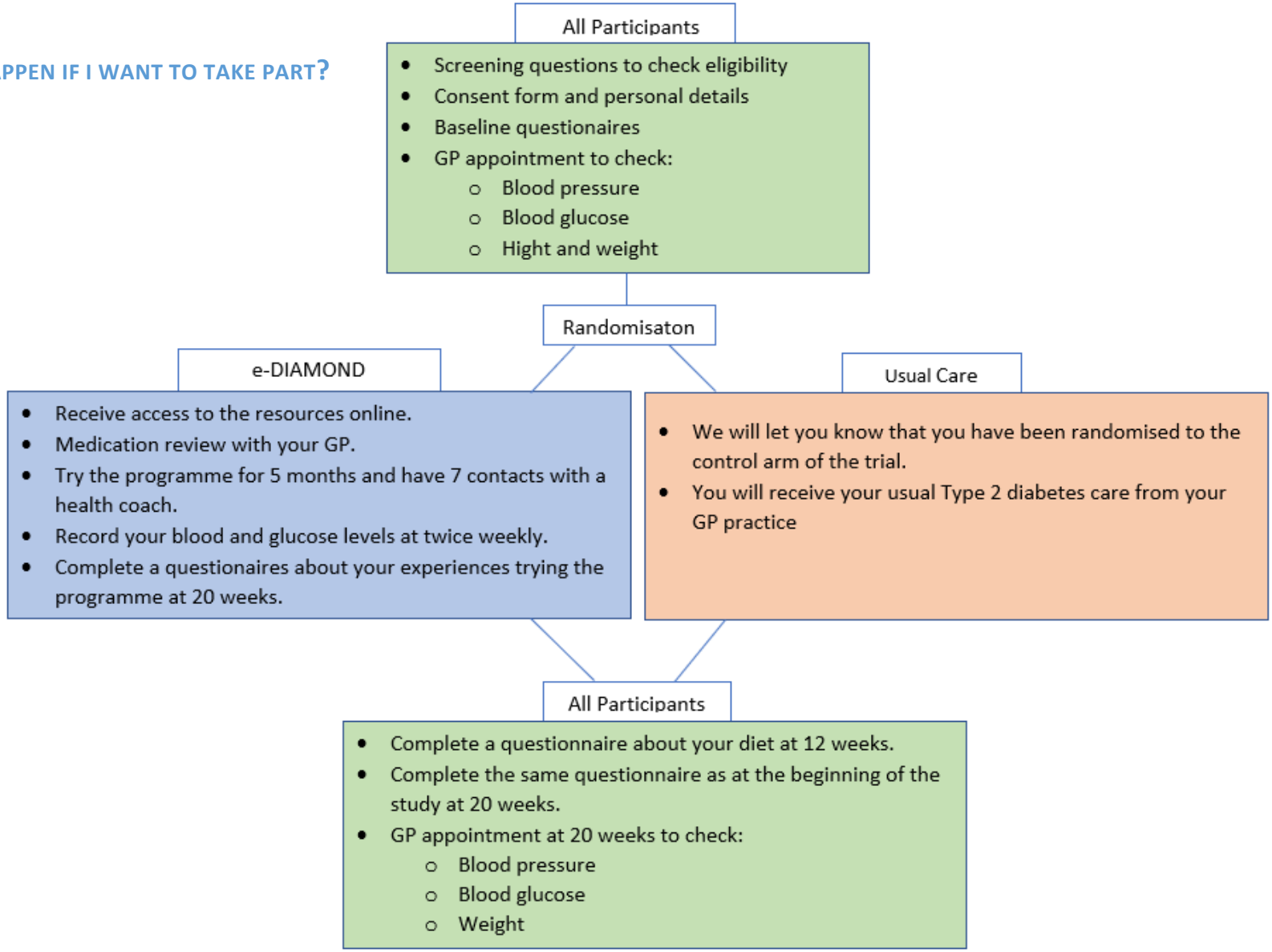
DO I HAVE TO TAKE PART?

- 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.

- 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 decide that you want to take part, please carry on reading and at the end of this page you will find a **link** to the study website (www.phc.ox.ac.uk/research/participate/eDIAMOND) and some questions to check if you may be suitable to take part. If you are, we will ask you to sign a consent form agreeing to take part in the study. You will be able to download a copy of the signed consent form to keep for your records.

1. Once you have completed and signed the consent form you will be given a link to complete some questionnaires, which should take less than 35 minutes. These questions ask you for general details about you, your health, and your feelings about having diabetes, as well as some questions about what you ate and drank the previous day.
2. We will ask you for information about you (your full name, email address, phone number, and which GP practice you are registered at) so that we can let your practice know that you have decided to take part. A member of staff from your GP practice will then contact you to book an appointment at your GP practice for a blood test) to check your blood glucose control and cholesterol levels) and to have some measurements taken (including your blood pressure, and your weight). The visit will take around 15 minutes, and we will try to coincide it with a routine visit.
3. Once your practice confirms you have attended this appointment, you will be randomly assigned to one of two groups. Half of people taking part will receive the new programme (**the eDIAMOND "intervention"**) as well as their standard NHS diabetes care, and the other half of people in the study will continue to just receive their **standard NHS diabetes care**.
4. If you are allocated to the new eDIAMOND programme, we will contact you to let you know based on your preferred method of communication– this can be via text, phone or an email. We will send your contact information to the provider of the new programme, who will then contact you (again, via your preferred method of communication) to help you access the programme for free. The online programme involves advice about your diet and behaviour change strategies to support you to manage your health and diabetes. If you take certain medications for blood pressure or diabetes, your GP may telephone you near the start of this programme to review these medications with you.

   During the 5 months of the programme, the health coaches will contact you via phone or video call (like Zoom or Microsoft Teams) 7 times to check how you are doing and to give you support or ask any questions you might have. You will be able to organise with the coach when this calls take place so they are convenient for you. These conversations with the health coaches will take place at the beginning of the intervention, and at 2, 4, 8, 12, 16 and 20 weeks. These conversations will be audio recorded to help us check that the programme is being delivered as we expect it to be, and to help us see if anything is not working well. During this time we will also have to record your blood glucose and blood pressure, so you will have to measure these values at your own home, twice a week, using the monitors we will send to you. You will be able to keep the glucose and blood pressure monitors after the study has

finished. However, if you wish to keep using the blood glucose monitor, you will need to purchase the glucose testing strips yourself. If you do not wish to keep your monitors, you will be able to return them to your GP practice.

5. Your GP will still be responsible for your care and making sure that you are safe during the study. If either the study team or the hub coach from the NewDAWN service identify any information that may suggest any safety issues, they will inform your GP to make sure there is no risk of harm.
6. Sometimes when people change their diet, they can feel a little light headed or unwell while their bodies get used to the new diet. If you feel unwell whilst undertaking any changes for the study, you are advised not to drive. However please note that in our previous studies testing a similar low-carbohydrate diet, people have not felt unwell enough not to drive.
7. At around half way of the study (at 12 weeks) all participants from both groups will be asked to complete again the online food intake.
8. After 5 months, participants from both groups (eDIAMOND and standard NHS diabetes care) will be sent a link via email or text to a follow-up questionnaire (that takes up to 30 minutes to complete). If we don't hear from you within 7 days, we may contact you again (via email or text or phone) to remind you. People who try the eDIAMOND programme will be asked to complete a short (5 minute) survey about the programme to give us their feedback. Note that this short survey is in addition to the other 3 questionnaires.
9. Around this time, both groups will be contacted to book another appointment at their GP practice for the same measurements to be taken as at the start of the study (blood pressure, weight, blood test). If needed, we may write, email, text or phone you with a reminder. If you do not attend these appointments for any reason, we may (with your permission) contact your GP practice to request details of your weight, blood pressure, or blood test measurements (that we would have been checked at your appointment) that you may have had as part of a routine visit to your GP. Please note that these measures are in addition to the normal care you receive from your GP.
10. If you are in the intervention group, the company running the programme will send us information about which parts of the programme you used so that we can look at what people found helpful. The company delivering the programme will be Reed Wellbeing who are already commissioned by the NHS to deliver weight loss and diabetes programmes on behalf of the NHS. The Reed Wellbeing staff that deliver the eDIAMOND programme have a Level 3 qualification in the field of health such as health improvement or nutrition. They have also received additional training in behaviour change from Reed Wellbeing plus specific training on eDIAMOND by topic experts in the University of Oxford study team. All information that they receive about you will be kept confidential, on secure servers, and only staff that work directly with the programme will be able to see any of your information. Any data the health coach collects during the programme will be entered into a database that is owned and hosted by the University of Oxford. The recordings of the conversations with the health coach will be transferred directly to the University of

Oxford, and once they have been received, Reed will delete them from their system, and will not be allowed to use them. All methods of transferring data will have to be approved by the University of Oxford, and all data will be processed in accordance with UK GDPR and the Data Protection Act (2018). Reed Wellbeing will not contact you about anything other than this study, and they will not keep your contact details after the study has finished.

11. Your participation in the study ends after the 5 months appointment and questionnaire. At this point you will receive a £20 voucher as a thank you for taking part. In addition, reasonable travel expenses to any other research-related appointments, should these be necessary, will also be reimbursed.
12. At the end of the study, you will continue with your usual care from your GP.

Your views

After the 5 months, a few people who participated and completed the eDIAMOND programme will be asked to take part in a telephone or online interview (the participants can choose their preferred method) to understand their feelings about the eDIAMOND programme and how it helped or did not help to manage their diabetes. 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. People taking part in these interviews will receive an additional £10 voucher as a thank you. We will keep this conversation strictly confidential and anonymous, only the researcher will know you participated in this interview.

WHAT SHOULD I CONSIDER?

- If you decide to take part, you should be willing to try to change your diet to improve your blood glucose level, and should not be planning to get pregnant or breastfeed in the next 12 months.
- If you decide to take part, you will be in the study for about 5 months.
- 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, have certain types of diabetes-related eye problems, or have developed a serious medical condition within the last 3 months (like a heart attack, stroke, cancer, or heart failure).
- We will go through a list of questions with you on the next page to check the programme is suitable for you, or you can get in touch with us and our research team can check any answers that you are not sure about with your GP.
- This study requires the use of computer and internet, as well as blood glucose and blood pressure monitors at home, so you need to have computer skills and feel confident with technology.

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. You will be able to take part as long as your GP practice is still recruiting for the study. If your GP practice has stopped recruiting for the study, unfortunately you will not be able to take part.

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.

- If you are asked to follow the eDIAMOND programme and you agree to do so, your GP may decide to reduce some of your usual medications based on your blood pressure and blood glucose readings – this is to avoid the risk of your blood pressure or blood glucose becoming too low. However they will discuss this with you before making changes, and you will be able to monitor your blood pressure and blood glucose levels to check your response to these changes. 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 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?

- The knowledge gained in this study will help us know how best to help people with type 2 diabetes in the future.

Will I be reimbursed for taking part?

You will be offered a £20 voucher for at the end of the study, as a way of reimbursing you for your time and any expenses in travelling to the appointment. If you take part in an interview you will be offered an additional £10 voucher as a thank you. In addition, reasonable travel expenses to any other research-related appointments, should these be necessary, will also be reimbursed, even if you drop-out of the study before it ends.

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?

- Yes. 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. We will only use your personal information where this is necessary to contact you. Information that can identify you will be only be held by the study team in a secure database for the purposes of the study. Confidentiality will be maintained as far as it is possible, unless you tell us something which implies that you or someone you mention might be in significant danger of harm. In this case, we would have to inform the relevant agencies, but we would discuss it with you first.

- Responsible members of the University of Oxford and the relevant NHS Trusts may be given access to data for monitoring and/or audit of the study to ensure that the research is complying with the applicable 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. GP staff will then enter the results of your blood test into the secure research database hosted by the University of Oxford. The hospital destroys your samples after analysis, just like they do when blood samples are taken as part of normal NHS care.

All blood samples will be taken, handled, analysed and disposed of according to standard NHS procedures and local practice policy.

What will happen to my data?

- 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 is the sponsor for this study. It 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 and other central NHS registries in order to undertake this study and will use the minimum personally-identifiable information possible.
- UK General Data Protection Regulation (UK GDPR) 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, based in the United Kingdom is the sponsor for this study and the data controller and is responsible for looking after your information and using it properly.

- We will store any research documents with personal information, such as consent forms, securely at the University of Oxford for 3 years after the end of the study, the study is expected to end in November 2024, as part of the research record.
- We will keep any other identifiable information about you for 6 months so that we can send you a summary of the study after the study has finished.

- Your information held with Reed Wellbeing will be retained for 12 months (even if you drop out of the study) to allow the performance of the programme to be analysed by the study team. Reed will not use your details to contact you about anything other than the eDIAMOND programme.

- The local study team and the eDIAMOND provider will use your contact details to contact you about the research study, and to oversee the quality of the study.
- A copy of the consent form from this study will be kept in your medical records for as long as those records are retained.
- You might be invited to take part in a telephone interview about the study. If you take part in these, they 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 by an approved external transcriber, with confidentiality and conduct contract in place with the University. The transcripts will be stored on secure servers at the University of Oxford

- If you are in the programme, the conversations between yourself and the hub coach will be recorded, as described earlier. These recordings will be transferred directly to the University of Oxford via a secure transfer method. Reed Wellbeing will delete the recording as soon as the research team has confirmed that it has transferred successfully. No one outside of the research team will listen to these conversations. These recordings will be transcribed by a member of the study team and the recordings and transcripts will be stored on secure servers at 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: e-diamond@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.

If you are assigned to the eDIAMOND interventions, you may choose to stop the study interventions but may remain on the study follow-ups. You may also withdraw from the study completely. If you wish to withdraw, **your information held with Reed Wellbeing will be retained for 12 months following cease of use to allow us to analyse the performance of the programme.**

We will use the data that has been collected from you up to the point at which you decide to withdraw from the study unless you request that we do not do so. 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 type 2 diabetes. The NHS already is developing different programmes and may use the eDIAMOND programme as one of the ways to help those patients, if we show that it is a helpful option.
- 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 with you if anything unexpected was found.

What if there is a problem?

If you have a concern about any aspect of this study, please speak with research team on 01865 289281 or email e-diamond@phc.ox.ac.uk . They will do their best to answer your questions.

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 study team or chief investigator, Dr Nicola Guess on 01865 289281 or e-diamond@phc.ox.ac.uk ; or you may contact the University of Oxford Research Governance, Ethics and Assurance (RGEA) office on 01865 616482 or email the director of RGEA at RGEA.complaints@admin.ox.ac.uk

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 University of Oxford is sponsoring this study. The present study is funded by the National Institute for Health Research (NIHR) Programme Grant for Applied Research. Dr Nicola Guess from 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 funders 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 protectparticipants' interests. This study has been reviewed and given favourable opinion by East of England - Cambridge East Research Ethics Committee.

Further information and contact details:

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

Contact Name: Daisy Harrison
Tel: 01865 289281
Email: e-diamond@phc.ox.ac.uk

Thank you for taking the time to read this information.

If you are happy that you would like to take part in this study, please follow the link below which will take you to some questions to check if you may be suitable to take part.

eDIAMOND — Nuffield Department of Primary Care Health Sciences, University of Oxford