



The **RESULT** study

REmote SUPport for Low-carbohydrate Treatment of type 2 diabetes

Participant Information Sheet

- We would like to invite you to take part in our research study.
- We are looking for people with type 2 diabetes, who would be willing to make changes to their diet to lose weight, and feel able to use a simple smartphone app or internet website to access information.
- This study is looking at what happens to people's blood glucose levels and general health when they follow a new diet, supported by a health coach and information via an app (accessed by smart phone or computer)
- As part of this study, half of the people who participate will be given free access to a 3 month remote support programme designed for people with type 2 diabetes, where you will be given the information and support you need to help you change your diet and lose weight, aiming to improve your diabetes and general health.
- Before you decide if you would like 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 the information below, and discuss it with others if you wish. If there is anything that is not clear, or if you would like more information, please contact us.
- At the bottom of the page you will find a link to confirm if you would like to take part

Our contact details

Professor Paul Aveyard – Chief Investigator

University of Oxford, Nuffield Department of Primary Care
Health Sciences, Radcliffe Observatory Quarter,
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Tel: 01865 617131 **Email:** RESULT@phc.ox.ac.uk

The RESULT Study– Full details

What is the purpose of the study?

Type 2 diabetes is a common disease in which a person's blood sugar levels are too high. We know that what we eat affects our blood sugar levels, and that changing our diets and losing weight can both help to control diabetes. However, it is not clear what the best advice is to help people achieve this goal, or what the best route to provide support with this is.

We want to study whether a support programme delivered remotely (via a simple mobile phone app or internet website) can help people with type 2 diabetes to change their diet and lose weight. This study will compare a new 3 month "intervention" (a change in diet, supported by a health coach and nutrition and health information through a simple smartphone app or website, run by an independent company), with the current routine dietary advice and NHS care.

What does the study involve?

The study will compare a 3 month diet and support programme, accessed via a simple smartphone app, with usual NHS care. The app and support programme gives you information on how you can change your diet to lose weight and improve your diabetes (and includes specific recipe ideas as well as information and advice), ways to track your progress, and the option to chat with a health coach or group of people trying to follow the same diet. You will be randomly allocated (like tossing a coin) to either try the new programme, or to continue receiving your usual care. You will not be able to choose which group you are in.

Most parts of the study will be completed online – including signing up to say you would like to take part, and completing 3 sets of questionnaires over a one year period (see the section below "[What will happen to me if I do decide to take part](#)" for details). However, everyone who takes part in the study will also be asked to attend 3 appointments at their GP practice (when they first start taking part, after 3 months, and after 12 months) to have a blood test and some routine measurements taken (like blood pressure and weight). These measurements are already part of your routine NHS diabetes care at least once each year, and the results will be available to your practice team as part of your NHS medical records.

Why have I been invited?

Your GP has sent this letter to you because you might be eligible to take part. We are looking for 100 people from across the UK to take part in this study.

What should I consider?

To be able to take part in the study, we need to confirm that you meet the following criteria:

- Have type 2 diabetes
- Are an adult aged 40 years or above
- Are overweight, with a body mass index (BMI) of 27kg/m² or higher (or 30kg/m² if you are of white ethnicity) (*you do not need to know your BMI yourself, we will check this if you decide you would like to take part*)
- Are able to use and have access to a mobile phone, computer or tablet with access to the internet. For the **online programme** to work best, you need to have a smart phone or tablet which runs any Android or Apple (iOS) operating systems.
- Would like to make changes to your diet or lifestyle to improve your diabetes control, lose weight, or improve your general health.

- Do not have any **medical conditions** that might make the programme we are testing unsuitable for you (e.g. taking insulin, diabetes-related eye problems or a recent serious medical condition). When you follow the link to see if you are eligible to take part, we will ask you a list of questions to check you are able to take part in the study.

The University of Oxford did not have access to any of your personal or medical information to send this letter – it has come directly from your GP.

Do I have to take part?

No, it is up to you whether you take part or not. If you decide not to take part you will not be contacted about this study again. Taking part in the study will not affect the usual care you receive from your GP for any other conditions.

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.

What will happen to me if I do decide to take part?

1. If you decide that you want to take part, please carry on reading and at the end you will find a **link** to some questions to assess whether you can take part. If you have any questions, our contact details are at the top of the first page. If you are eligible to take part you will be asked to provide your full name, email address and confirm which GP surgery you are registered at. You will then be given an access code which you will be required to write down and keep in a safe place. If you are ineligible you will be told when you complete the eligibility assessment. This will take about 3 minutes to complete.
2. The study team will send you an **email with a link to the consent form** where you will need to enter your full name and access code. You will be asked to agree to the items in the consent form and enter your full name and access code to consent to the study. You will be able to download a copy of the consent form to keep for your records.
3. Once you have completed the consent form you will be given a link to complete some **questionnaires** which will take no longer than 30 minutes. If you don't complete the questionnaires you will not be able to continue in the study. You will have to complete the questionnaire fully in one attempt as the system will not allow you to go back into the questionnaires to answer later. However, you do not have to complete the questionnaires and dietary recalls at the same time as completing the consent form. These questions ask you for general details about you, your health, and your feelings about having diabetes. The last questionnaire ("Intake 24") to complete will be a 24 hour recall food diary. This means that you will be asked about the food and drink that you have consumed the day prior to completing this questionnaire.
4. We will then contact your GP to inform them that you are interested in taking part and have completed the online consent and questionnaire forms. 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, cholesterol levels and liver function) and to have some measurements taken (including your blood pressure, and your weight). The visit will take around 15 minutes, and if it can be timed to coincide with a routine visit you are already due, it will be.
5. Once your practice confirms you have attended this appointment, you will be randomly (that is, as if by chance, like tossing a coin) assigned to one of two groups. One will receive the new programme (the "intervention") and the other will receive standard NHS clinical care.

6. If you are assigned to try the **new programme (intervention group)**, we will send you an email to let you know. If you are assigned to the new programme, we will send your contact information using a secure email system to the provider of the new programme, who will then contact you 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. After 3 months, we may contact you to ask you if you would be willing to take part in a telephone interview to discuss your experiences of the programme, but taking part in this is optional (you can indicate if you'd be happy to be contacted about this on the consent form during the next step). After 3 months, you will retain access to the digital content within the online programme and therefore will still have access to any data or materials used throughout the first 3 months. However, enhanced access to the programme and the utilisation of the personalised health coach will cease after 3 months.
7. Both groups, after **3 months** and **12 months**, will be sent a link to a **follow-up questionnaire** (that takes up to 30 minutes to complete). If we don't hear from you, we may write, text or phone you to collect the information.
8. Both groups, after **3 months** and **12 months**, will be contacted by a member of staff from their GP practice to **book another appointment at their GP practice** for the same measurements to be taken both times (blood pressure, weight, blood test) as at the start of the study. If needed, we may write, email, text or phone you with a reminder. The total volume of blood we will collect at each visit is the same as you have taken for your routine diabetes check blood tests, and the blood test will be done by a trained nurse or healthcare worker at your practice following standard NHS procedures. If you do not attend these appointments for any reason, we may (with your permission) contact your GP surgery to request the results of any weight, blood pressure, or blood test measurements (that we would have been checking at your appointment) that you may have had as part of a routine visit outside the trial.
9. If you are in the intervention group we will be sent information from the company running the programme (including any weight tracking readings you have submitted, and which parts of the programme you used) so that we can look at what people found helpful.
10. Your participation in the study ends after the 12 months appointment and questionnaire. At this point you will receive a £20 voucher as a thank you for taking part

If you have any difficulties with any of the online forms, or with accessing the online programme if you are allocated to this group, you can contact the study team using the details at the top of this information sheet, and we will do our best to help you.

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.

If you are successful in losing weight or lowering your blood glucose levels during your participation in this study, your GP may decide to suggest reducing 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 any 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.

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.

When you attend your GP surgery for a blood test, as with any blood test, 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?

There may be no direct benefit to you as a result of taking part in the study. However, we hope this study will help us to understand whether this programme, and others like it, could be an option to help future people with type 2 diabetes who are trying to change their diet and improve their health and blood glucose control, as one of the treatment options available from the NHS.

If you are allocated to receive the new programme, you may lose weight and improve your blood glucose levels, which can be beneficial to your health and wellbeing.

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

Your GP practice will be notified of your participation and with your consent, will share specific information from your electronic health record relating to the study outcomes with us.

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 a participant code instead of your name.

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

Will I be reimbursed for taking part?

Once you complete your 12 month GP surgery visit and questionnaire you will receive a £20 gift voucher as a thank you for taking part in the study.

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 data controller and is responsible for looking after your information and using it properly.

We will be using information about you in order to undertake this study and will use the minimum personally-identifiable information possible. This includes the personal information you gave us in order to be able to contact you again (e.g. your name and contact details), and the information discussed above that will be pseudonymised for the research study once extracted from your medical records. We will keep identifiable information about you securely at the University of Oxford for up to 12 months 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 up to 5 years after the end of the study after which they will be deidentified.

Basic engagement data (for example which bits of the app you use) will be stored by the company providing the programme; they will share this data with us as part of the study so that we can look

Study: RESULT study

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Chief Investigator: Professor Paul Aveyard

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across all participants (not at an individual level) to see which parts of the programme were used more often or appeared to be more helpful. The company who provides the intervention will have your contact details for the purpose of enrolling you into the intervention. The contact details that we send to the programme provider will be sent securely, using an end-to-end encrypted email. All other identifiable information, which will be provided by yourself, is governed by the privacy policy of the intervention provider. When you sign up with the programme, the company will also be processing your data according to their privacy policy, available at secondnature.io/terms. The provider will retain any information held on an individual for up to 10 years after that individual has ceased use of the System. At that point, your information will be deleted. As covered in section 5 of the providers privacy policy, you may request that personal information is deleted at any time. If you request this deletion during the study, this will lead to your withdrawal from the research.

The company ("Intake24") who design the food intake questionnaire will store your answers to these questionnaires for the duration of the study. This information will be given to us securely using identification codes that only the study team can link back to you – the company will not have access to (or ask for, or store) any of your personally identifiable information.

If you are in the intervention group and agree to a short telephone interview, this will be audio-recorded, and then transcribed. The transcriptions will be pseudonymised 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 audio recordings will be kept securely until data analysis has finished, and then will be deleted.

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 the study team at RESULT@phc.ox.ac.uk

What will happen to the samples I give?

The blood samples will be analysed to measure your blood sugar levels and HbA1c together with other markers of general health, including liver function, and cholesterol levels. The samples will be processed in the usual way for blood tests sent by your GP practice, and the results sent to your GP with your consent. If any changes in your blood samples are found, such as changes in blood glucose, HbA1c or cholesterol, these will be returned directly to your GP practice and communicated with you or treated accordingly. After this, the samples will be destroyed and will not be used for other purposes.

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 use the data that has been collected up to the point at which you decide to withdraw from the study unless you specifically request that it is destroyed. We will still access your medical records up until the point that you decide you would like to withdraw from the study, even if you do not attend follow-up appointments at 3 and 12 months. In the event that you withdraw from the study and have been assigned to the intervention group, the intervention provider will retain all details provided by yourself and the study team for 10 years from last login, unless requested otherwise. You will be free at any time to request that your personal information is deleted by contacting either the study team or intervention provider directly.

What will happen to the results of this study?

The results of this study may help us to understand more about how changes in diet for people with type 2 diabetes can affect their blood glucose levels and general health, and whether this programme is an effective way to support changes in diet and lifestyle. The project will also contribute to a doctoral thesis (research qualification) on this subject at the University of Oxford. The overall study results may be presented at scientific meetings or published in a scientific journal. You will not be identified in the presentations and publications. We will send a summary of the results to you if you would like a copy, and this will also be available to view on the study website.

What if there is a problem?

The University of Oxford, as Sponsor, has appropriate insurance in place in the unlikely event that you suffer any harm as a direct consequence of your participation in this study. NHS indemnity operates in respect of the clinical treatment which is provided. Clinical treatment refers to the standard care that you will receive throughout the duration of this study.

If you wish to complain about any aspect of the way in which you have been approached or treated, or how your information is handled during the course of this study, you should contact the study team at RESULT@phc.ox.ac.uk or 01865 617131, or you may contact the University of Oxford Clinical Trials and Research Governance (CTRG) office on 01865 616480, or the head of CTRG, email ctrig@admin.ox.ac.uk.

Who is organising and funding the study?

The Chief Investigator is Professor Paul Aveyard who is a GP and works in clinical research at the University of Oxford. This study is funded by the National Institute for Health Research (NIHR) Biomedical Research Centre (BRC) in Oxford, and the Wellcome Trust. The University of Oxford is the study sponsor.

Who has reviewed the study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect participants' interests. This study has been reviewed and given favourable opinion by West Midlands - Solihull Research Ethics Committee.

Further information and contact details:

If you want to discuss the study in more detail please contact Professor Paul Aveyard or a member of the study team on: 01865 617131 or RESULT@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 assess whether you can take part.

[LINK TO ELIGIBILITY CHECK](#)