

Evaluating the NHS Digital Diabetes Prevention Programme

Participant Information Sheet (PIS)

You are being invited to take part in a research study investigating what people think about the NHS Digital Diabetes Prevention Programme. Before you decide whether to take part, it is important for you to understand why the research is being conducted and what it will involve. Please take time to read the following information carefully before deciding whether to take part and discuss it with others if you wish. Please ask if there is anything that is not clear or if you would like more information. Thank you for taking the time to read this.

About the research

➤ **Who will conduct the research?**

This research is being led by the School of Health Sciences at the University of Manchester and supported by the Department of Primary Care and Population Health at University College London. The researchers carrying out this research are Dr Jamie Ross and Professor Elizabeth Murray.

➤ **What is the purpose of the research?**

Type 2 diabetes is a common problem. The NHS have brought in new services to help prevent Type 2 diabetes, including the 'Healthier You' Diabetes Prevention Programme (NHS DPP) to help people make changes to their lifestyle (e.g. diet and exercise). The NHS DPP have since released a new framework to expand the programme and improve take-up and adherence to the NHS DPP, including the implementation of digital support for diabetes prevention alongside existing face-to-face provision: NHS Digital Diabetes Prevention Programme.

The NHS needs to know why or why not people decide to join this programme, their experiences of joining and what could be improved to help more people make use of the programme. We have designed a project which will help answer these questions.

You have been invited to take part because you have been offered the NHS Digital Diabetes Prevention Programme. You may have been offered it via your GP practice, by taking the "Know Your Risk" type 2 diabetes risk score, or directly by the providers of the programme.

It does not matter if you have decided to join the programme or not – we are interested in the views of all people who are offered the course including those who have joined, those who have decided not to join the programme, and those who might decide to join it at another time. We intend to interview up to 30 people in total.

➤ **Will the outcomes of the research be published?**

We will study the interviews of all the people we talk to about the NHS Digital Diabetes Prevention Programme and will develop a set of 'themes' that describe overall views and experiences of the programme. These findings will be written up as articles for publication in scientific journals and as a report for the funder of the research. The findings will also be presented at scientific conferences, and might be summarised as an online blog article. A

report of the findings will be sent to study participants who wish to receive them and who agree to this on the consent form.

➤ **Who has reviewed the research project?**

This study has been reviewed and approved by the North West - Greater Manchester East Research Ethics Committee NHS Research Ethics Committee (ref. 17/NW/0426).

➤ **Who is funding the research project?**

The study is funded by the National Institute for Health Research as part of the DIPLOMA research programme at the University of Manchester.

What would my involvement be?

➤ **What would I be asked to do if I took part?**

If you agree to take part a researcher will interview you about your views and experiences of the NHS Digital Diabetes Prevention Programme. You will also be asked questions about your views and experiences of pre-diabetes and type 2 diabetes.

The interview will be carried out over video call (such as Zoom, Teams or Skype), or over the telephone. If deemed safe under current Covid-19 restrictions, interviews may also take place in person, at a place convenient for you (e.g. at home, work, or a suitable community location), so there will be no extra travel or costs for you to take part. The interview will be audio-recorded and will last up to one hour.

Before the interview starts the researcher will check whether you have any final questions and ask for your signed consent (or verbal consent if taking part over the phone or video call) for recording the interview and using the recording as described in this information sheet. The interviewer will also ask you to fill out a short questionnaire about your background and health. The interview will include questions about your decisions to take part (or not) in the NHS Digital Diabetes Prevention Programme, your experiences of accessing the course (if relevant), and questions about your views and experiences of pre-diabetes and type 2 diabetes.

➤ **Will I benefit from taking part?**

As a thank you for taking part, you will be offered £25 for participating in the interview. This will be offered as a high street shopping voucher.

What happens if I do not want to take part or if I change my mind?

It is up to you to decide whether or not to take part. If you would like to take part you can contact the researcher, Dr Jamie Ross, using the contact details at the end of this information sheet. If you do decide to take part you will be given this information sheet to keep and will be asked to sign a consent form or to provide verbal consent if taking part by telephone or video call.

If you decide to take part you are still free to withdraw at any time without giving a reason and without detriment to yourself. However, it will not be possible to remove your data from the project once it has been anonymised and analysed as we will not be able to identify your

specific data. This does not affect your data protection rights. If you decide not to take part you do not need to do anything further. As the interviews need to be audio-recorded for use in the study, it is not possible to take part without the interview being recorded. However, if you become uncomfortable with the recording process you are free to stop the interview and the recording at any time.

Data Protection and Confidentiality

➤ What information will you collect about me?

In order to participate in this research project we will need to collect information that could identify you, called "personal identifiable information". Specifically we will need to collect:

- Your name, contact details and postal address (e.g. to arrange the interview, to send you a report of the findings)
- An audio-recording of your voice and any identifiable names/places mentioned in the interview

We will also ask to complete a brief questionnaire containing questions about you and your health. This will allow us to describe the people who take part in this study. This data will be identified only by an ID number.

All information collected about you during the research will be kept strictly confidential. You will be assigned an ID number. This pseudo-anonymised (key-coded) information will be collected, stored, handled and processed by the research team at The University of Manchester and University College London. You will not be able to be identified in any ensuing reports, publications, lectures or presentations.

Under what legal basis are you collecting this information?

We are collecting and storing this personal identifiable information in accordance with UK data protection law which protect your rights. These state that we must have a legal basis (specific reason) for collecting your data. For this study, the specific reason is that it is "a public interest task" and "a process necessary for research purposes".

➤ What are my rights in relation to the information you will collect about me?

You have a number of rights under data protection law regarding your personal information. For example you can request a copy of the information we hold about you, including audio recordings.

If you would like to know more about your different rights or the way we use your personal information to ensure we follow the law, please consult our data protection notices: <https://www.manchester.ac.uk/discover/privacy-information/data-protection/privacy-notice>

Will my participation in the study be confidential and my personal identifiable information be protected?

- **Will my participation in the study be confidential and my personal identifiable information be protected?**

In accordance with data protection law, The University of Manchester is the Data Controller for this project. This means that we are responsible for making sure your personal information is kept secure, confidential and used only in the way you have been told it will be used. All researchers are trained with this in mind, and your data will be looked after in the following ways:

- Only the study team at The University of Manchester and University College London will have access to your personal information (contact details, consent form/recording, and interview recording). Your name and any other identifying information will be removed from the transcript of the interview. The transcript will be labelled with a random ID number. This ID number will represent you, but only the research team will have access to the key that links this ID number to you. This ID number will not be combined with other information in a way that could identify you. The information will only be used for the purpose of this study, and cannot be used to contact you regarding any other matter. Any information to you disclose in the interview will be kept strictly confidential and will not be used to identify you in any way. Research data from this study will be stored for 5 years after the last publication of the study or for 10 years, whichever is greater.
- The interview will be recorded using an encrypted audio recorder. Your verbal consent will be taken via a separate audio recording to the interview recording, using an encrypted audio-recorder. Audio-recorded verbal consent will be stored separately from the research data. The consent statements will be read aloud individually, and you will confirm Yes or No to each statement. All optional consent statements will be made clear. Audio-recording files will be assigned an ID number only known to the research team and stored on password-protected computers within the University of Manchester and University College London. Audio-recorded verbal consent will be stored on a secure University of Manchester server, only accessible to the research team. Physical consent forms will be stored in a locked filing cabinet in the private office of one of the research team at the University of Manchester or University College London. These storage procedures will take place as soon as the researcher conducting the interview returns to their office at the University of Manchester or University College London. Your contact details will be deleted as soon as no longer needed. The interview recording and your audio-recorded verbal consent will be retained for 2 years after the end of the study.
- When you agree to take part in a research study, the information you have shared in the interview may be provided to researchers running other research studies in this organisation. The future research will be of a similar nature to this research project and will concern the evaluation of the Diabetes Prevention Programme or the content of interventions designed to help people change diet and exercise behaviours. Your information will only be used by this organisation and researchers to conduct research in accordance with the UK Policy Framework for Health and Social Care Research: <https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/>. This information will not identify you and will not be combined with other information in a way that could identify you. The information will only be used for the purpose of research, and cannot be used to contact you regarding any other matter.

- The audio-recording will be typed into a transcript of the interview by an external company (based in the UK) who is an approved supplier for the University of Manchester, and with whom there is a confidentiality agreement in place between them and the University. All personal identifiable information such as names and places will be removed from the final transcript.
- Please also note that individuals from The University of Manchester or regulatory authorities may need to look at the data collected for this study to make sure the project is being carried out as planned. This may involve looking at identifiable data. All individuals involved in auditing and monitoring the study will have a strict duty of confidentiality to you as a research participant.

What if I have a complaint?

➤ Contact details for complaints

If you have a complaint that you wish to direct to members of the research team, please contact: Dr Jamie Ross, 020 8016 8037 Jamie.Ross@ucl.ac.uk (researcher), or Prof. Elizabeth Murray, 020 8016 8025, Elizabth.murray@ucl.ac.uk (head of the research study)

If you wish to make a formal complaint to someone independent of the research team or if you are not satisfied with the response you have gained from the researchers in the first instance then please contact: The Research Ethics Manager, Research Office, Christie Building, The University of Manchester, Oxford Road, Manchester, M13 9PL, by emailing: research.complaints@manchester.ac.uk or by telephoning 0161 306 8089.

If you wish to contact us about your data protection rights, please email: dataprotection@manchester.ac.uk or write to The Information Governance Office, Christie Building, The University of Manchester, Oxford Road, M13 9PL at the University and we will guide you through the process of exercising your rights.

You also have a right to complain to the Information Commissioner's Office about complaints relating to your personal identifiable information: <https://ico.org.uk/make-a-complaint> or telephone 0303 123 1113.

Contact Details

If you have any queries about the study or if you are interested in taking part then please contact the researcher:

[Dr Jamie Ross](mailto:Jamie.Ross@ucl.ac.uk), 0208 016 8037 Jamie.Ross@ucl.ac.uk (researcher).