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PARTICIPANT INFORMATION SHEET FOR PATIENTS

NewDAWN: **New remission care pathway: Diabetes Adaptive Weight management Network**

We'd like to invite you to take part in our 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.

Summary

For people recently diagnosed with type 2 diabetes (T2D) who are overweight, losing weight can put diabetes into remission. Remission means your diabetes has gone away so you have healthy blood glucose without taking medication. However, diabetes can still come back in the future so you would still have annual diabetes checks at your practice. This study is to see whether offering people services in a new service (NewDAWN) can help more people achieve remission, compared with the current best, gold-standard which is offered by the NHS. Participants in the study will be asked to attend three appointments at their GP practice and we will decide by chance whether you attend the gold-standard treatment for achieving diabetes remission or attend the NewDAWN service. Both options will support and guide participants to lose weight and keep the weight off and improve their diabetes.

What is the purpose of the study?

In some parts of the UK, the NHS offers one type of weight loss programme to help people with diabetes achieve remission. We want to test whether offering a range of weight loss programmes can help more people to achieve T2D remission.

Why have I been invited?

Everyone in your area who has been diagnosed with T2D within the six years and who is overweight has been invited by their GP to discuss the benefits of T2D remission and whether to take part in this research. If you are willing to lose weight to try to put your diabetes into remission then we would be very pleased if you join our study.

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 works with GP practices across the UK, of which your practice is one, which help to identify people who may be suitable and interested in taking part in research.

The study will involve 1,788 patients.

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 before you start the trial. You are free to stop the treatment or withdraw from the study at any time without giving a reason. A decision to withdraw from the study will not affect the usual clinical care you receive from your GP or practice nurse or other healthcare professional.

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

If you decide to take part, you will need to attend the GP practice a minimum of 3 times approximately every six months, lasting 10-20 minutes, where the nurse will take measurements and a blood test.

At your first appointment, the staff at your GP practice will:

- Take your weight and height
- Take your blood pressure
- Record what medications you are currently taking
- Record your answers to some questionnaires to understand your quality of life and how you manage your diabetes (this will take about 5 minutes to complete).
- Take a blood sample (this will only be about 2 teaspoons of blood) to measure your blood glucose and cholesterol. If you have had a heart attack or stroke we also take a blood test for CRP which is a measure of inflammation in the body.
- Your first appointment will take approximately 40 minutes

We will also send you a link to complete an online dietary questionnaire, this should take you less than 15 minutes to complete. We will send you up to 2 reminders.

In joining the trial, we ask only that you commit to hearing about what the weight loss programme involves and attending your practice for the assessments at 6 months and 12 months, even if you do not join the weight loss programme. If you agree to join the study we will randomise you to one of two groups. Randomisation is like tossing a coin. It means that neither you or your doctor or nurse will get to choose which group you go into. You will be offered a programme to put your diabetes into remission whichever group you are allocated to.

If you are allocated to the first group (gold standard treatment), a health coach will tell you about the programme by letter, text message or phone call, depending on the area you live in. It will be up to you to decide whether or not to try this having heard about it. The health coach on the programme will support and guide you through your weight loss journey; this may be through phone calls, video calls, and app, or in face to face appointments, depending on the area you live in.

If you are allocated to the second group (NewDAWN service), your GP practice will refer you to a weight-loss hub coach who will contact you by phone to tell you about the NewDAWN programme and you can decide whether to follow this approach. You will have regular phone calls with your hub coach to help support and guide you through your weight loss journey.

In both programmes (gold standard treatment and NewDAWN service) the coach will guide and support you to make changes to what you eat over a few months to help you lose weight and then support you to keep the weight off.

If you do not want to be involved in the programmes after you have heard about them, you will be free to go back to your GP and see if there is anything else that they are able to offer you, now or in the future if it is not the right time for you at the moment.

The hub coach will audio record your calls to them, with your consent, to help improve the support they give to people.

Everyone will be asked to go back to their GP practice **at 6 and 12 months after being enrolled in the study** to repeat the same measurements that were taken at the start of the programme, including the online questionnaire, so we can assess any changes. Clinical members from your GP practice will:

- Take your weight
- Take your blood pressure
- Record what medications you are currently taking

- Record your answers to the same questionnaires to understand your quality of life and how you manage your diabetes.
- Take a blood sample (about 2 teaspoons of blood) to measure cholesterol and blood glucose (HbA1c).

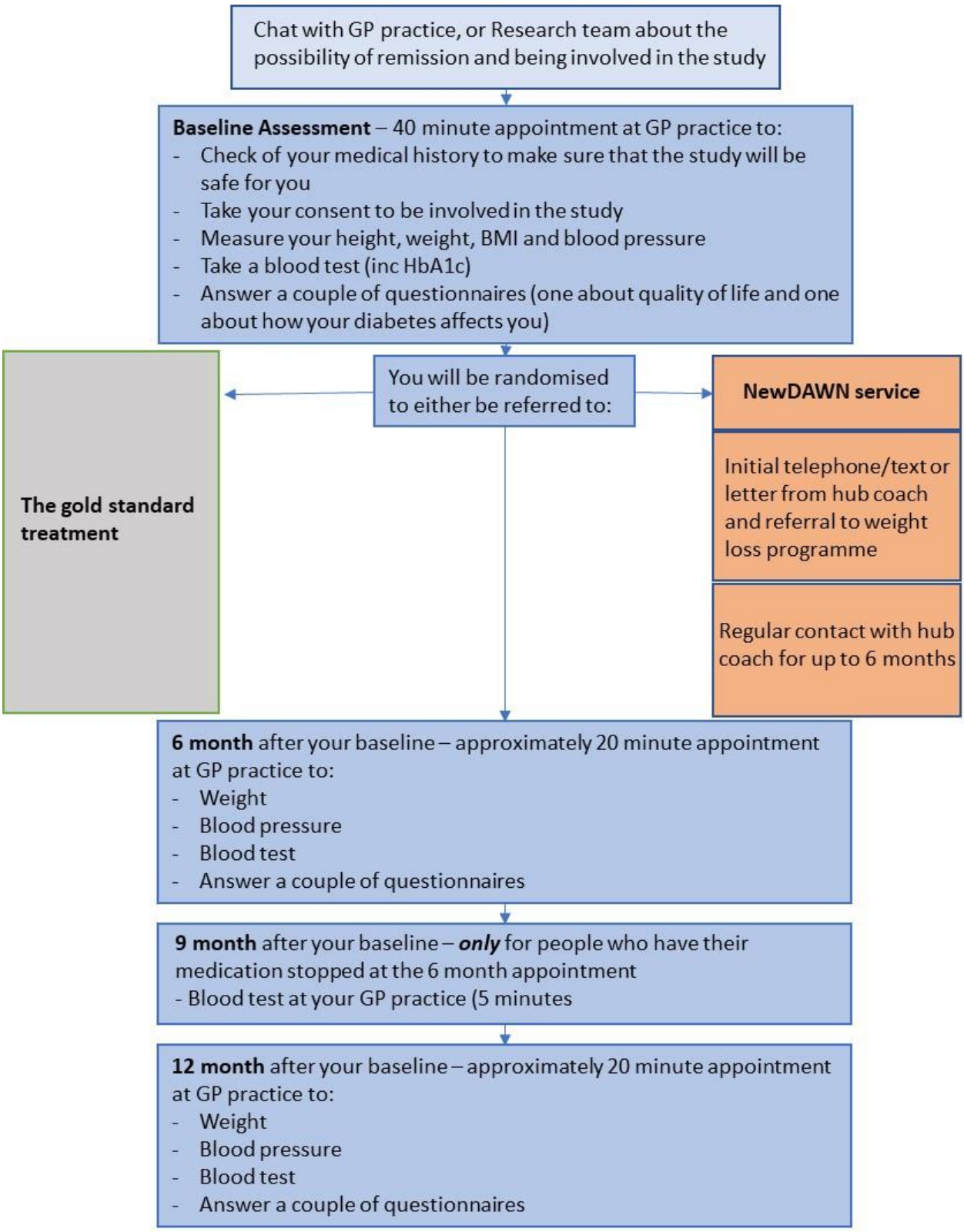
If you stop your diabetes medication at the 6-month appointment, we will ask you to have an extra blood test at the GP practice 3 months later.

After the study has finished, you will need to continue to see your GP for your regular diabetes check-ups, even if you are in remission. Being in remission means that your blood glucose levels are now normal or near normal, but this does not mean you are cured from diabetes. Diabetes can return in the future and your GP practice will give you an annual check for this.

Finally, we will ask you to consider talking to one of our researchers from the University of Oxford. They will ask you about your experience of the weight loss programmes and the coach. The one-off discussion will be over the phone for about **30 minutes**. The researchers will audio-record this discussion with your consent to make best use of the information you provide. The discussion will be kept confidential and only the researchers will know that you have taken part. This is to help us understand what the NewDAWN service did well, and how it could be improved.

As part of this study, we would like to see if these programmes benefit your health long-term. For this we will look at specific section of your medical records (those relating to your diabetes) to see how you are getting on. You will not need to do anything for this, we will ask the NHS to give us this information. We will do this for up to 20 years after the study has finished.

NewDAWN Participant pathway



If you do not wish to be involved in these programmes, you will be able to return to your GP at any time to discuss your care and options with them

What should I consider?

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 weight loss programmes 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,
- have developed a serious medical condition within the last 3 months (like a heart attack, stroke, cancer, or heart failure).
- you are breastfeeding or planning to get pregnant in the next 12 months, this is not the right treatment for you at this time.
- Taking medications to help you lose weight that you started less than 3 months ago.
- you are taking part in a similar study (if you are in a study and not sure how similar it is, please speak to the research team or your GP practice).

When you speak to a staff member at your GP practice at your first visit, they will go through a list of questions with you to check the programme is suitable for you.

Are there any possible disadvantages or risks from taking part?

There are **no known serious risks** from the weight loss programmes on offer in this study. All the weight loss programmes are offered in parts of England to people in the NHS with no serious side effects. Sometimes when people change their diet, they can become constipated. If you take part in these weight loss programmes, your coach will advise you how to prevent this happening or help you manage it if it occurs.

Some of these weight loss programmes can reduce your blood pressure and blood glucose substantially and that means we may advise you to reduce or stop your medication for blood pressure or diabetes. The NHS has procedures for this to make sure it is safe. Some of the weight loss programmes may ask you to monitor your blood glucose and blood pressure so you can alert your doctor or nurse if these are out of range and your medication may need to be reviewed.

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 distress you.

As with any blood sample extraction, there is possibility that you may develop some bruising around the area and some people faint while the sample is taken. Appropriate support will be available to you if needed.

What are the possible benefits of taking part?

- We hope that you will benefit personally from taking part in this study. Everybody who takes part will be offered the opportunity to join a weight loss programme that could mean they go into remission from their diabetes, meaning normal blood glucose levels without needing diabetes medication
- You will receive additional blood tests as part of an enhanced health screening check. We will share the results with you and your doctor who can arrange any further treatment you may need if a problem is detected.
- In addition, by taking part in this research study you will be helping us work out how best to help people with T2D in the future so that more people can achieve remission from diabetes.

Will my general practitioner/family doctor (GP) be informed of my participation?

Your GP will invite you into the study and will know if you decide to take part in it. Your doctor will get the results of your blood tests throughout the study. Taking part in the study will not affect the clinical 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. All study records and samples will be identified only by a code. We will only use names, date of birth, and/or NHS numbers where this is necessary, for example to link to your NHS records to you and to contact you about the study. Information that can identify you will only be held securely by the research team for the purposes of the study. We will use codes to avoid identifying you with your name. The publications about the study results will not identify you.

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 appropriate regulations.

More details can be found in 'What will happen to my data?' section below.

Will I be reimbursed for taking part?

Yes. To thank you for your time, you will receive a £25 voucher for attending the 6-month appointment and another £25 voucher after you have attended the 12-month appointment. You will also get a £20 voucher for any interview that you complete. The vouchers are for a range of shops.

What will happen to my data?

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, based in the United Kingdom is the sponsor for this study and 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 store any research documents with personal information, such as consent forms, securely at the University of Oxford for at least 5 years and possibly up to 20 years after the you have finished the study, as part of the research record.

If you agree to your details being held to be contacted regarding future research, we will retain a copy of your consent form securely until such time as your details are removed from our database. We will keep the consent form and your details separate from one another and any research data.

We will keep any other identifiable information about you including your NHS number to allow us to link our records to related health records in the future, we will hold this data for at least 5 years and up to 20 years. We will also keep your contact details for at least 6 months after the study has finished so that we can let you know the results of the study and if you agree to be contacted about future research studies, we will also need your contact details for this reason.

The study team based at the University of Sheffield will use your pseudonymised research data to assess the weight loss programmes' value for money, this means that they will not know be able to identify you in this data. They will have no access to your personal data.

Your GP practice and/or the local study team will use your name and contact details to get in touch with you to arrange appointments.

A copy of the consent form from this study will be kept in your medical records for as long as those records are retained.

We will audio record the phone calls between you and your health coach, and if you are invited and choose to take part in a 30-minute discussion with one of the researchers these will be audio recorded too, with your prior consent. The recordings will then be transcribed by a University approved transcriber, with a confidentiality and conduct contract in place with the University. Your name will be removed from the transcriptions and will be replaced with a

unique code number as soon as possible, so you will not be identified by your name, only by this unique code number. Any recordings presented in publications, teaching or training will be subject to further anonymisation (e.g. modulating voices, removing identifying information such as date and location) so you will not be identified from any recording placed in the public domain.

If you join the study and are referred to the gold standard treatment or the NewDAWN service, we will pass your information onto a provider who runs the service and employs the weight-loss coaches. This provider will be a third party that provides other NHS programmes, and is subject to all NHS data protection governance. They will have a contract in place with the University, and will not be allowed to use your data for any activities other than those they are contracted to deliver, and will not be allowed to use your information for any marketing or advertising reasons.

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 NewDAWN study team newdawn@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.

In addition, **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 decide to withdraw, you have 3 different options. You can withdraw:

- from the intervention (any treatment you are receiving in the NewDAWN service or gold standard service), but still attend the follow up visits at your GP practice for example at 6 and 12 months
- from the intervention and all follow up visits, but allow us to link data we gathered in the study to your medical records
- from all the intervention sessions, all follow up visits, and not allow us to collect data from medical records in the future.

A researcher will contact you and ask you what you would like to do.

If at any time you want to withdraw from the study, we will use the pseudonymised data (without your name on it, only with the unique ID code) that has been collected up to the point at which you decide to withdraw from the study. This includes the data from any interviews you may have already taken part. We would continue to use this anonymised data after your withdrawal from the study.

What will happen to the results of this study?

We will use the knowledge gained from this study to help us and the NHS to design care pathways to offer better treatments to patients with T2D. We plan to publish our findings in lots of different places including academic journals, present them at conferences or to healthcare professionals and we will also put up a summary of our findings on a website for you and the other members of the public to read about. **You will not be identified in any report** or publication from this study.

What if we find something unexpected?

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

What if there is a problem?

If you have a concern about any aspect of this study, please speak with research team. 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 example, through the study-specific use of monitoring equipment we have leant you, like blood pressure monitors and scales). NHS indemnity operates in respect of the clinical treatment provided.

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 Prof Susan Jebb 01865 617826 or NewDAWN@phc.ox.ac.uk or you may contact the University of Oxford Research Governance, Ethics and Assurance (RGEA) office on rgea.complaints@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 contact the PALS team please contact them at PALS@ouh.nhs.uk or get in contact via their website http://www.ouh.nhs.uk/patient-guide/pals.aspx

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

Patients living with T2D were involved in the design of the study from the beginning. We also have a person living with T2D as a co-investigator on the study team. In addition, we spent a period of seven months interviewing people living with T2D about the NewDAWN service so we could make sure the new service meets the needs of patients. Finally, we have set up a patient advisory group comprised of five patients living with T2D who oversee the study, and who provide feedback and guidance from the perspective of the patient. You can find more information at www.crn.nihr.ac.uk/can-help/patients-carers-public/how-to-take-part-in-a-study/

Who is organising and funding the study?

The University of Oxford is sponsoring the study and is responsible for the design, conduct and publication of results from this study. The present study is organised by Prof Susan Jebb from the Nuffield Department of Primary Care Health Sciences at the University of Oxford. The study is funded by the National Institute for Health Research (NIHR).

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 South Central – Oxford B Research Ethics Committee.

Participation in future research:

We may want to see how participants in this study are getting on in the future, or we may have other studies similar to this study that you might be interested in. If you agree, we may contact you in the future to ask whether you would be interested in being involved in another study. The research team would contact you to ask you about being involved, but by agreeing to be contacted does not mean that you have to be involved in the research. It will still be your choice. You can also be removed from this register any time that you wish. If you agree to being contacted in the future, your contact details would be held securely, in a password-protected folder, with restricted access, separate from any other study data on a secure network at the University of Oxford.

Further information and contact details:

Please contact the NewDAWN study team on 01865 289206 or email NewDAWN@phc.ox.ac.uk

Thank you for considering taking part.