**Questionnaire Participant Information Leaflet for people who attended**

**Study title: Understanding Participation in the National Digital Diabetes Prevention Programme**

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You are being invited to take part in a research study to be carried out by Dr Sheena McHugh, Senior Lecturer and Researcher and Clair Haseldine, PhD student at the School of Public Health, UCC, Cork.

Before you decide whether or not you wish to take part, you should read the information provided below carefully and, if you wish, discuss it with your family, friends or doctor. Take time to ask questions – don’t feel rushed or under pressure to make a quick decision.

You should clearly understand the risks and benefits of taking part in this study so that you can make a decision that is right for you. This process is known as ‘Informed Consent’.

You don't have to take part in this study. If you decide not to take part it won’t affect your current or future medical care.

**Why is this study being done?**

This study is evaluating the new national diabetes prevention programme in Ireland. It will look at who is taking part in the programme and why people do or do not take part.

The plan for the national programme is to try out the programme with 10 courses to start in 2021 and then to expand it further in 2022. Taking part in diabetes prevention programmes has been shown to reduce the risk of developing type 2 diabetes for those at high risk but for the programme to make a difference in the overall health of the population many people need to take part. Your answers will help us to understand the reasons you decided to take part and this information will help when the national programme expands to include more people.

**Who is organising and funding this study?**

This study is being sponsored by University College Cork (UCC) and is being carried out by researchers from the School of Public Health in UCC. The study is being funded by the Health Research Board. TheHealth Research Board is a State Agency under the Department of Health.

**Why am I being asked to take part?**

You are being asked to take part in this study because you were invited to take part in the new national diabetes prevention programme which is being delivered online. Understanding why people do or do not participate in the national diabetes prevention programme is important for improving the service for others.

**How will the study be carried out?**

If you agreed to be contacted by researchers when you started the diabetes prevention programme you will be sent a questionnaire in the post. In recognition of completing the questionnaire you can claim a shopping voucher worth €10. The details of how to do this are on the second page of the questionnaire. The questionnaire will be accompanied by an invitation letter, this information leaflet, and a consent form.

We will examine the information in the questionnaires to see what reasons people have for participating or not in the programme. This information will be useful for understanding what plans need to be made to make the programme available to more people at risk of diabetes in Ireland.

The questionnaire will be sent out to people who were invited to attend the diabetes prevention programme in 2021 (approximately 130-150 people).

**What will happen to me if I agree to take part?**

If you agree to take part, you will fill out the questionnaire. It should take 10 to 15 minutes to complete. You can send it back with the consent form in the stamped addressed envelope addressed to the researcher Clair Haseldine in UCC.

At the start of the questionnaire it asks for your contact details. There are two reasons for this, firstly, to send out the shopping vouchers and secondly, to invite you to participate in a follow up focus group discussion or interview.

For privacy, your completed questionnaire will be assigned a number (pseudoanonymised) when we receive it and kept separate from your contact details.

If you agree to the vouchers but not the invite to participate in the focus group or interview, we will delete your contact details after posting the vouchers to you otherwise we will keep them for the full duration of the study.

**What are the benefits and risks of taking part?**

Benefits: Type 2 diabetes is a serious chronic disease which places a huge burden on individuals and health systems. Increasing the participation in diabetes prevention programmes is key to making an impact on the disease. Sharing your thoughts on the programme may improve participation in the national programme in the future.

Risks: The risks attached to the study are minimal. It is a low-risk study of the implementation of routine services being provided by the HSE. Only personal data that is necessary to the research objectives will be collected. There is a risk that a connection to your identity could be made but care will be taken to avoid this by anonymising the questionnaires and keeping them separate from your contact details.

If you find any of the questions sensitive in nature you can leave them blank. If you should feel any distress while filling out the questionnaire you can contact your healthcare provider to follow up.

**What if something goes wrong when I’m taking part in this study?**

The sponsor of the study, University College Cork, has appropriate insurance in place if you are harmed as a result of participation in this study. The normal Health Service Executive complaints mechanisms will be available to you if appropriate.

**Will it cost me anything to take part?**

It will not cost you anything to take part in the study.

**Will my data be kept confidential?**

Your identity will remain confidential. A study number will identify you. Your name will not be published or disclosed to anyone. No identifying material will be used in any reports of this study. Records for the study will be kept in a password protected UCC OneDrive (online storage file). The investigator and researchers working on the study will have access to your study data. Authorised staff, who work for UCC may require access to your details or study records to ensure that the study is being conducted in accordance with relevant regulations and Irish law.

**What will happen to the results of the study?**

The results of the study will be anonymised. Study information will be reported in aggregate and may be published in peer reviewed journals and used for presentations or conferences, however, neither you nor your information will be identifiable in any report that arises from the study.

**Who has reviewed this study?**

All patient focused research in Ireland is reviewed by an independent group of people called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by the Clinical Research Ethics Committee of the Cork Teaching Hospitals. They can be contacted at: Clinical Research Ethics Committee of the Cork Teaching Hospitals, Lancaster Hall 6 Little Hanover Street, Cork. The Clinical Research Ethics Committee can be contacted at telephone no: [021-4901901](about:blank), email: [crec@ucc.ie](mailto:crec@ucc.ie)

**Where can I get more information?**

If you need any further information about the study now or in the future, please contact:

**Clair Haseldine PhD Student or Dr Sheena McHugh**

**Study telephone no: 086 031 8227**

**Email:** [**chaseldine@ucc.ie**](mailto:chaseldine@ucc.ie)[**S.McHugh@ucc.ie**](mailto:S.McHugh@ucc.ie)