PARTICIPANT INFORMATION LEAFLET

Feasibility trial of an intervention to improve attendance at diabetic retinopathy screening

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We would like to invite you to take part in a research study to test a strategy to improve attendance at retinopathy screening. Before you decide you need to understand why the research is being done and what it would involve for you. Please take time to read the following information carefully. Ask questions if anything is not clear or if you would like more information. You can change your mind about taking part in the study any time you like, without giving reason.

WHY IS THIS STUDY BEING DONE?

Screening is an essential part of diabetes management yet uptake in Ireland is only 61%. Strategies to improve screening uptake can be effective. The purpose of this study is to test a strategy to improve attendance at diabetic retinopathy screening. We want to pilot a strategy in different practices to determine whether it is possible to deliver it in a real-life practice.

WHO IS ORGANIZING AND FUNDING THIS STUDY?

This research is being conducted by a research team based in the School of Public Health, University College Cork. A lot of our research is focused on health services and ways that services can be improved. The study is funded by the Health Research Board (HRB), a government agency that funds health research.

WHY IS OUR PRACTICE BEING ASKED TO TAKE PART?

We want to examine the feasibility of the intervention in different settings. Your practice has been invited to take part because it has certain characteristics (e.g. size) that we are interested in.

HOW WILL THE STUDY BE CARRIED OUT?

Eight practices will be randomly assigned to be either an intervention or wait-list-control practice. If your practice is in the intervention group your practice will try the strategy over a 6-month period. If you are in the control group your practice will deliver usual care and try the new strategy after 6 months. The strategy involves a few different components 1) a briefing on study procedures for practice staff (20-minutes and training on audit (a one-hour session with a staff member responsible for conducting the audit); 2) electronic alerts on patient files; 4) face-to-face or phone reminders, followed by a GP-endorsed letter and a key information sheet for people with diabetes who have not attended screening. To inform the delivery of the strategy your practice will need to conduct an audit at baseline and re-audit at 6 months to identify patients with diabetes who have not attended screening and any changes in attendance. Using date restricted data extraction from the electronic medical record, control practices will collect audit data

for the 12-month period before introducing the strategy (study baseline) and 6 months afterward the study period during which they will have acted as control practices (follow-up). Control practices will receive the same supports and training as intervention practices.

WHAT WILL HAPPEN IF OUR PRACTICE AGREES TO TAKE PART?

- Your practice will be asked to conduct an audit of adult (≥ 18 years) patients with diabetes to identify those who have not been registered, have not consented or have not attended the screening service using electronic medical records where available, and verified with the national screening service dedicated telephone line if necessary. Data will be collected on key demographics and screening status. If there are many patients with diabetes at your practice, we ask that you audit a random sample of 100 patients. The audit cycle has been piloted in a large primary care centre and takes on average 5-10 minutes per patient. You will need to conduct a re-audit at 6 months.
- We will brief staff at your practice on the procedures for delivering the strategy (20 minutes).
- We will provide support to your practice including an audit protocol and a tailored audit training session (1 hour) delivered by the research team with the staff member responsible for the audit.
- We will ask staff at your practice to deliver reminders to patients face-to-face or over the phone and follow up with a letter and information sheet (provided by the research team).
- Your practice will be reimbursed for conducting the audit, making phone calls, issuing letters and other items such as postage.
- To evaluate the strategy and the costs associated, we will ask staff at your practice to provide a summary of how the strategy is being delivered; i.e., who has been assigned to certain tasks, approximately how long they take, and whether any other resources have been used.
- Once the study is completed (after 6 months) you will be invited to complete a short questionnaire on the acceptability, appropriateness and feasibility of the strategy, and to take part in an interview.

WHAT ARE THE POSSIBLE BENEFITS OF TAKING PART?

The overarching aim is to develop a feasible and acceptable strategy to increase the uptake of screening, which is an essential to prevent or delay the development of diabetic retinopathy. Taking part will give your practice an opportunity to potentially improve uptake of retinopathy screening among your patients

with diabetes. Your practice will be reimbursed for the costs of taking part and will receive training and support. By taking part, you can fulfil your requirement for your annual Irish Medical Council audit, or for internal CPD.

WHAT ARE THE POSSIBLE RISKS OF TAKING PART?

We do not think there will be any negative consequences for your practice, and we would like to assure you that we are available to answer any questions throughout the study. Your practice will be asked to conduct an audit and to deliver a strategy which will take time. However, your practice will receive training and on-going support from the study team, copies of all the required materials, and will be reimbursed for the cost of conducting the audit and delivering the strategy. Your practice can decide locally who will carry out the audit.

DO YOU HAVE TO TAKE PART?

No, participation in this study is completely voluntary. Even if your practice decides to take part, it may stop taking part at any time during the trial. You can withdraw permission to use the information you provide within one month of data collection, in which case the information collected will be deleted.

WILL TAKING PART BE CONFIDENTIAL?

Yes, your participation in this study will be private and confidential. The only people that will know you are taking part will be the research team. Your data will be kept confidential and stored securely as an encrypted file in the School of Public Health. No practices, professionals or patients will be personally identified in any public reporting of the study results. Anonymised results will be published in an international peer-reviewed journal and will be presented at research meetings and conferences.

DATA PROTECTION

The purpose of the study is to test an intervention to improve attendance at diabetic retinopathy screening. This study is being conducted in the public interest (General Data Protection Regulation 2016 Article 6(1)(e)); and for scientific research purposes (General Data Protection Regulation 2016 Article 9(2)(j)).

The data will be accessed, analysed and stored by the School of Public Health, University College Cork. Your data will be stored for ten years, as per the UCC code of research conduct. Your data will be kept

confidential and stored securely as an encrypted file in the School of Public Health. We do not think that there will be any risks or implications for you that will arise as a result of collecting and storing your data.

You have a right to withdraw consent to use the information provided within one month of signing the consent form, in which case this information will be deleted. You have a right to have any inaccurate information corrected. You have a right to request access to your data. If you wish to withdraw consent, correct information, or access your data, you can contact a member of the study team (details below). You have the right to lodge a complaint with the Data Protection Commissioner. You have a right to receive your data in a format which allows you to provide it to another party for analysis. Anonymized results will be published in an international peer-reviewed journal and will be presented at research meetings and conferences. No practices, professionals or patients will be personally identified in any public reporting of the study results.

WHO SHOULD YOU CONTACT FOR FURTHER INFORMATION?

If you have any further questions, please do not hesitate to contact us:

[Designated UCC researcher and contact details]

Address: School of Public Health, 4th Floor Western Gateway Building, University College Cork.

Tel:

Email:

THANK YOU

CONSENT FORM

FEASIBILITY TRIAL OF AN INTERVENTION IMPROVE ATTENDANCE AT DIABETIC RETINOPATHY SCREENING

Please tick

1. I agree to participate in this trial. ☐
2. I confirm that I have read and understood this information sheet and have had the opportunity to ask questions. ☐
3. I understand that my participation in this study is voluntary. I am free to withdraw at any time during the study, without providing a reason. ☐
4. I understand that I can withdraw permission to use the information provided within one month of signing this consent sheet, in which case the information provided will be deleted. ☐
5. I agree that my anonymised data will be used to evaluate the delivery of intervention, examine the intervention feasibility, and in publications, reports, and presented at conferences and meetings ☐
6. I understand that the data I provide will be stored securely for 10 years, as per the UCC Code of Research Conduct ☐
7. I understand that under the freedom of information act, I am entitled to access the information provided by me at any time while it is in storage as specified above. ☐
8. I understand that I am free to contact any of the research team to seek further clarification and information. ☐
9. I give informed explicit consent to have my data processed as part of this research study. ☐

Participant Signature	Name in Block Capitals	Date
Researcher Signature	Name in Block Capitals	Date