PARTICIPANT INFORMATION LEAFLET

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

Principal investigator's name:	Dr Sheena McHugh
Principal investigator's title:	Lecturer
Telephone number of principal investigator:	021 4205526
Co-investigator's name:	Dr Fiona Riordan
Co-investigator's title:	Post-doctoral Researcher
Data Controller's/Joint Controller's Identity:	Dr Sheena McHugh
Data Controller's/Joint Controller's Contact Details:	021 4205526
Data Protection Officer's Identity:	Catriona O'Sullivan
Data Protection Officer's Contact Details:	021 4903949 | foi@ucc.ie

We would like to invite your practice to take part in a research study. 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. Please ask questions if anything is not clear or if you would like more information. You can change your mind about taking part 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 in the School of Public Health, University College Cork. Our research focuses on health services and ways that services can be improved for patients. 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 are interested in examining the feasibility of using this strategy in different practice settings. Therefore, your practice has been invited to take part because it has certain characteristics we are interested in (e.g. size).

HOW WILL THE STUDY BE CARRIED OUT?

Eight practices will be randomly assigned to be either an intervention or 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 all adult (≥ 18 years) patients with diabetes to ascertain those who have not been registered, have not consented or have not attended the screening service from 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 will ask you audit a random sample of 100 patients. 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 your practice with support and training to conduct the audit. We will provide you with a written audit protocol and one of our research team will deliver a tailored audit training session (1 hour) with the staff member responsible for the audit
- We will ask GPs and nurses at your practice to deliver reminders to patients face-to-face or over the phone and follow-up with a GP-endorsed letter and brief information sheet. We will provide your practice with copies of all materials, including a short, scripted message, letter and information sheet.
- 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 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 (at 6 months) we will ask all staff to complete a short questionnaire on the acceptability, appropriateness and feasibility of the strategy and invite some staff members 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 I 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 study. You can withdraw permission to use the information provided by the practice within one month of data collection, in which case the information collected will be deleted.

WILL TAKING PART BE CONFIDENTIAL?

Yes, your practice's participation in this study will be private and confidential. The only people that will know your practice is taking part will be the research team. Your practice 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 a strategy 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)).

Data will be accessed, analysed and stored by the School of Public Health, University College Cork. All data will be stored for ten years, as per the UCC code of research conduct. Patient data will be anonymised within your practice and removed from the practice on an encrypted laptop. The researchers will only have access to anonymised patient data. Practice data will be kept confidential and stored securely as an encrypted file in the School of Public Health. We do not envisage any risks or implications will arise as a result of collecting and storing data from your practice.

Practices have a right to withdraw their 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 the 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 the data in a format which allows you to provide it to another party for analysis.

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. Our practice agrees 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 our practice's participation in this study is voluntary. The practice is free to withdraw at any time during the study, without providing a reason.	☐
4. I understand that our practice 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 anonymised data from our practice will be used to deliver the intervention, examine the intervention feasibility, and in publications, reports, and presented at conferences and meetings	☐
6. I understand that the data our practice provides 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 the practice 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 our practice data processed as part of this research study. ☐

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