ISRCTN73168630 https://doi.org/10.1186/ISRCTN73168630

Identifying and contacting people living with diabetes in Canada who may need their eyes examined for signs of retinopathy: a mixed methods study

Submission date 28/04/2025	**Recruitment status** Recruiting	[ ] Prospectively registered [ ] Protocol
Registration date 01/08/2025	**Overall study status** Ongoing	[ ] Statistical analysis plan [ ] Results
Last Edited 22/07/2025	**Condition category** Eye Diseases	[ ] Individual participant data [X] Record updated in last year

Plain English summary of protocol

Background and study aims

Over time diabetes may cause changes in the back of your eyes and blur your vision (known as diabetic retinopathy). By examining your eyes on a regular basis, these changes can be detected and, if needed, treatments can be provided to prevent blindness. The Canadian recommendation for individuals with diabetes is to monitor their eyes once a year, but not all individuals with diabetes have their eyes checked on a regular basis. This study is using provincial health information available to identify individuals who have not had your eyes examined by an eye care professional (for example, an ophthalmologist or optometrist) within the last 425 days (1 year and 2 months) and will be contacted by your primary care practitioner about eye care screening. The aim of the study is to increase the screening rate of individuals who are at risk for diabetic retinopathy within the primary care setting, and to refer to treatment for those at risk of vision loss.

Who can participate?

Individuals 18 years or older who are living with diabetes (Type 1 or Type 2) who have been identified in provincial databases (Alberta, Newfoundland & Labrador, British Columbia and Ontario) as needing their eyes looked at for retinopathy.

What does the study involve?

For those individuals who are called by their primary care centre, to have their eyes looked at for signs of diabetic retinopathy, they will be asked if they wish to either come to the centre for an appointment or referred to either an optometrist or ophthalmologists. If required, they will be sent for treatment. Some of the people contacted will also be asked if they are willing to participate in an interview or focus group to talk about their eye care and what they think about how the healthcare system supports their care or challenges they may have.

What are the possible benefits and risks of participating?

There are no direct benefits to participating in the study. The information learned from this

study may help patients in the future by improving health systems and delivery of eye screening for individuals living with diabetes. It is not possible to know all of the risks that may happen in a study, but the researchers have taken all reasonable safeguards to minimize any known risks to a study participant.

Where is the study run from?
The study is being run at primary care centres in Alberta, Newfoundland & Labrador, British Columbia and Ontario (Canada)

When is the study starting and how long is it expected to run for?
The study is starting to call individuals in Alberta in the summer of 2025 and will be beginning in Newfoundland & Labrador and British Columbia in 2026. Interviews are ongoing in Ontario. The study is scheduled to end in March 2027.

Who is funding the study?
The study is funded by the Canadian Institutes of Health Research and Diabetes Canada.

Who is the main contact?
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
NCT05074342

Secondary identifying numbers
Pro00132494

Study information

Scientific Title
Guiding primary care diabetic retinopathy screening in Canada through the use of provincial healthcare administrative data

Acronym
DRS in Canada

Study objectives
The provision of a diabetic retinopathy screening (DRS) status list to primary health care settings will increase the rate of annual DRS in patients with type 1 or type 2 diabetes who have attended the centres.

Ethics approval required
Ethics approval required

Ethics approval(s)
1. Approved 06/12/2023, Health Research Ethics Board (8440 112 St. NW, Edmonton, Alberta, T6G 2R7, Canada; +1 (0)780 492 3111; reoffice@ualberta.ca), ref: Pro00132494/pSite-23-0060

2. Approved 11/02/2021, University Health Network Research Ethics Board (700 University Avenue, 4th Floor, Toronto, M5G 1Z5, Canada; +1 (0)416 581 7849; reb@uhn.ca), ref: 20-5249

Study design
Longitudinal convergent mixed-methods comparative study using an implementation-effectiveness hybrid approach

Primary study design
Interventional

Secondary study design
Effectiveness-implementation hybrid design

Study setting(s)
Community, GP practice

Study type(s)
Screening

Participant information sheet

Health condition(s) or problem(s) studied
Diabetic retinopathy

Interventions
The diabetic retinopathy screening intervention consists of 1) participant identification using provincial healthcare administrative data to identify individuals, followed by 2) outreach by primary healthcare settings to contact the unscreened patients, explaining the need for retinopathy screening, and how it differs from a routine eye examination that they may have had previously for glasses and activate referral for retinopathy screening. Contact methods will be aligned with current practices within the primary health care setting, including telephone, direct mail, face-to-face appointments, and email and group sessions. 3) Diabetic retinopathy screening using local Tele-Retina services. 4) Program assessment and examination of the diabetic retinopathy screening and diabetic retinopathy treatment and other eye care utilization patterns and volumes up to 12 months following the completion of the outreach program.

Intervention Type
Other

Primary outcome measure
Clinical Evaluation Study:
Using provincial healthcare administrative data the following secondary clinical measures will be examined:

1. The proportion of individuals screened at 12 months following the DRS end of the intervention.
2. The average time in days for diabetic retinopathy screening, by optometrists, ophthalmologist or tele-retina after 12 months of follow-up from the end of the DRS intervention.
3. For those individuals identified, the proportion receiving treatment, the type of diabetic retinopathy treatment received, and time in days from the end of the DRS intervention.

Secondary outcome measures
Implementation Study:
Through the qualitative study and information collected in the semi-structured interviews, the following measures will be examined:
1. What are the facilitators and barriers to delivering the intervention?
2. What are the facilitators and barriers to sustaining the intervention after the study is completed?
3. How could this intervention be modified to facilitate adoption and sustainability?

Policy Study:
Policy-driven barriers and facilitators (funding/resource allocation/system infrastructure, billing, data transfer) associated with DRS intervention implementation and scale-up across other province(s). We will assess the current practice patterns for DRS and policy recommendations for health system change, if any, will be reported and discussed with stakeholders.

Economic Evaluation Study:
This evaluation will include a description of the cost of implementation of the DRS intervention, a cost-effectiveness analysis of the DRS intervention compared to usual care using propensity score matched-concurrent controls identified from healthcare administrative data, and a budget impact analysis to determine total program costs, cost per patient screened, and cost per DR case treated) using trial-based approach and economic modelling using a 6-month and 12-month time horizon.

Overall study start date
11/04/2019

Completion date
31/03/2027

Eligibility

Key inclusion criteria
1. At least 18 years of age
2. Type 1 or type 2 diabetes as determined through linked provincial healthcare administrative datasets or primary care data using algorithms similar to provincial methods
3. Attended the primary health care setting, with at least one visit to the centre within the past 10 years

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
2000

Key exclusion criteria
1. Individuals identified as having received diabetic retinopathy screening (in the previous 425 days) by an ophthalmologist and/or optometrist or tele-ophthalmology/Tele-Retina

Date of first enrolment
01/03/2025

Date of final enrolment
30/09/2026

Locations

Countries of recruitment
Canada

Study participating centre
Aspen Primary Care Network
202-10030 106 Street
Westlock, Alberta
Canada
T7P 2K4

Study participating centre
Edmonton West Primary Care Network
Meadowlark Health & Shopping Centre, Suite 124
156 Street & 87 Avenue
Edmonton, Alberta
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Sponsor information

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Sponsor type
Hospital/treatment centre

Website
http://www.uhn.ca/corporate/AboutUHN/OurHospitals/TGH

ROR
https://ror.org/04cm2y595

Funder(s)

Funder type
Government

Funder Name
Canadian Institutes of Health Research

Alternative Name(s)
Instituts de Recherche en Santé du Canada, Canadian Institutes of Health Research (CIHR), CIHR_IRSC, Canadian Institutes of Health Research | Ottawa ON, CIHR, IRSC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Canada

Funder Name
Diabetes Canada

Alternative Name(s)
DC

Funding Body Type

Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Canada

Results and Publications

Publication and dissemination plan
Taking an integrated knowledge translation approach with the group of knowledge users actively involved with all aspects of the project development, they will lead the translation of the study findings and disseminate knowledge products to their peers (e.g. educational (patients) and implementation toolkit for healthcare providers and organizations including government) to address practice and policy change. Our Patient Partners will play a crucial role in creating and disseminating culturally appropriate knowledge products (e.g. educational /informational toolkit for patients on the importance of DRS) to their peers. Working with the knowledge users, we will use the Knowledge Map to develop barrier-specific KT interventions including collaborative working groups, policy briefs, multidisciplinary educational outreach via webinars, videoconferences, workshops, awareness-building strategies for DRS (short promotional videos), and audit and feedback in addition to publications and presentations to increase knowledge flow, improve implementation, and enhance scalability and sustainability of our findings.

Intention to publish date
31/12/2027

Individual participant data (IPD) sharing plan
Some of the datasets generated and/or analysed during the current study are not expected to be made available as they are provincial healthcare administrative data.

IPD sharing plan summary
Not expected to be made available, Data sharing statement to be made available at a later date