

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	Recruitment status	<input type="checkbox"/> Prospectively registered
28/04/2025	Recruiting	<input type="checkbox"/> Protocol
Registration date	Overall study status	<input type="checkbox"/> Statistical analysis plan
01/08/2025	Ongoing	<input type="checkbox"/> Results
Last Edited	Condition category	<input type="checkbox"/> Individual participant data
06/01/2026	Eye Diseases	<input checked="" type="checkbox"/> 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 their 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?

Valeria Rac, Valeria.rac@theta.utoronto.ca or Valeria.Rac@uhn.ca

Donna Manca, dpmanca@ualberta.ca

Jim Bowen, jim.bowen@uhn.ca

Contact information

Type(s)

Principal investigator

Contact name

Dr Valeria Rac

ORCID ID

<https://orcid.org/0000-0002-0426-4594>

Contact details

200 Elizabeth Street

Toronto

Canada

M5G 2C4

+1 (0)416 634 8799

valeria.rac@theta.utoronto.ca

Type(s)

Scientific

Contact name

Dr Donna Manca

ORCID ID

<https://orcid.org/0000-0001-6073-7715>

Contact details

#6-10, 8303 112 St. NW (University Terrace)
Edmonton
Canada
T6G 2T4
+1 (0)780 492 8102
dpmanca@ualberta.ca

Type(s)

Public

Contact name

Mr James Bowen

ORCID ID

<https://orcid.org/0000-0002-6457-2337>

Contact details

200 Elizabeth Street
Toronto
Canada
M5G 2C4
+1 (0)416 634 8807
jim.bowen@uhn.ca

Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

NCT05074342

Protocol serial number

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

Study type(s)

Screening

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(s)

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.

Key secondary outcome(s))

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.

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

Healthy volunteers allowed

No

Age group

Mixed

Lower age limit

18 years

Upper age limit

110 years

Sex

All

Total final enrolment

0

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

31/03/2027

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
Canada
T5R 5W9

Sponsor information

Organisation

Toronto General Hospital Research Institute

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 - Welcome to the Canadian Institutes of Health Research, CIHR, IRSC

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Canada

Funder Name

Diabetes Canada

Alternative Name(s)

The Canadian Diabetes Association, Canadian Diabetes Association, DC, CDA

Funding Body Type

Government organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

Canada

Results and Publications

Individual participant data (IPD) sharing plan**IPD sharing plan summary**

Not expected to be made available