# A behaviour change technique reminder intervention for diabetic retinopathy screening

| Submission date<br>18/06/2025       | Recruitment status Recruiting  | <ul> <li>Prospectively registered</li> </ul> |
|-------------------------------------|--------------------------------|--|
|                                     |                                | ☐ Protocol                                   |
| <b>Registration date</b> 07/07/2025 | Overall study status Ongoing   | Statistical analysis plan                    |
|                                     |                                | Results                                      |
| <b>Last Edited</b> 24/06/2025       | Condition category Oral Health | Individual participant data                  |
|                                     |                                | [X] Record updated in last year              |

### Plain English summary of protocol

Background and study aims

This study aims to see if a specially designed health reminder can help encourage people with diabetes to get their eyes tested for diabetic retinopathy. These reminders will be designed with input from the community and translated into four different languages spoken by people in the downtown Ottawa community.

### Who can participate?

Adults (18+) who are registered in a local community diabetes education program can be sent a reminder

### What does the study involve?

Participants in the study will be randomly assigned to receive an email reminder or no reminder at all. The research will then compare how many people in each group attend and book an eye appointment. It is expected that the participants who receive a reminder will be more likely to attend /book an appointment.

### What are the possible risks and benefits of participating?

Participants will benefit from the opportunity to have their eyes tested, especially for those who did not know about diabetic retinopathy or were unable to get their eyes tested before. No risks are expected to be involved with participating in the study. At the end of the study, everyone, including those who did not receive a reminder during the study, will be told about the opportunity to have their eyes tested.

### Where is the study run from?

The study is being organized and managed at the Ottawa Hospital Research Institute. The eye appointment booking and patient data will be maintained at the Community Health Centre.

When is the study starting and how long is it expected to run for? May 2025 to March 2026

### Who is funding the study?

This study is being funded by the University Health Network (UHN) and Diabetes Action Canada.

Who is the main contact?

Dr. Justin Presseau, Ottawa Hospital Research Institute, jpresseau@ohri.ca

Dr. Jenny Olson, Ottawa Hospital Research Institute, jolson@ohri.ca

# Contact information

### Type(s)

Scientific, Principal Investigator

### Contact name

Dr Justin Presseau

### Contact details

The Ottawa Hospital Research Institute 501 Smyth Road

Ottawa

Canada

K1H 8L6

jpresseau@ohri.ca

### Type(s)

Public, Scientific, Principal Investigator

### Contact name

Dr Jenny Olson

### Contact details

The Ottawa Hospital Research Institute 501 Smyth Road Ottawa Canada

K1H 8L6

jolson@ohri.ca

# Additional identifiers

# **EudraCT/CTIS** number

Nil known

### **IRAS** number

# ClinicalTrials.gov number

Nil known

### Secondary identifying numbers

20250367-01H

# Study information

### Scientific Title

Evaluating the efficacy of a behaviour change technique-based and linguistically tailored e-mail-based reminder to increase attendance to diabetic retinopathy screening

### Study objectives

This study aims to answer the following:

Do linguistically adapted reminders that use behaviour change techniques help people with diabetes in Ottawa schedule and attend their eye screening appointments more than no reminder at all?

We expect that, compared to participants in the control group, who will not receive a reminder about diabetic retinopathy screening, participants in the intervention group, who will receive a reminder, will be more likely to book and attend a diabetic retinopathy screening appointment during the trial period.

### Ethics approval required

Ethics approval required

### Ethics approval(s)

Approved 15/05/2025, OHSN-REB (Ottawa Health Science Network Research Ethics Board) (Civic Box 675 725 Parkdale Avenue, Ottawa, K1Y 4E9, Canada; +1 613-798-5555 ext. 16719; REBAdministration@ohri.ca), ref: CRRF ID: 6493

### Study design

Single centre two-arm randomized controlled trial

# Primary study design

Interventional

# Secondary study design

Randomised controlled trial

# Study setting(s)

Community, Internet/virtual, Medical and other records

# Study type(s)

Screening, Efficacy

# Participant information sheet

# Health condition(s) or problem(s) studied

Diabetic retinopathy (DR)

### **Interventions**

Eligible participants will be randomly assigned to the intervention or control condition using SAS statistical software. Arm 1: Control Group - does not receive a reminder, and Arm 2: Reminder Group - receives a behaviour change techniques-based and linguistically tailored electronic reminder. Reminders are distributed using an electronic medical record-integrated patient

communications system, where participants receive a link to a webpage reminder encouraging diabetic retinopathy screening, booking, and attendance.

### Intervention Type

Behavioural

### Primary outcome measure

Diabetic retinopathy (DRS) screening attendance is measured using data pulled from a study-specific tab in the participants' electronic medical records, which tracks participant attendance and booking. DRS screening attendance will be measured at the end of the trial, after data collection has closed and the debrief has been sent to all participants.

### Secondary outcome measures

The following secondary outcomes are measured using data pulled from a study-specific tab in the participants' electronic medical records at the end of the trial, after data collection has closed and the debrief has been sent to all participants:

- 1. DRS appointment booking, tracked using participant attendance and booking
- 2. Subgroup analysis (age, gender/sex, language, prior DRS, distance to community health centre from place of residence in kilometers), tracked using these pre-selected patient demographic data

### Overall study start date

01/05/2025

### Completion date

30/03/2026

# Eligibility

### Key inclusion criteria

- 1. Are registered to the Community Diabetes Education Program of Ottawa at the community health centre
- 2. Have T1DM or T2DM
- 3. Have consented to virtual communications from CHC
- 4. Are 18 years of age or older
- 5. Have an active chart (i.e., chart has been updated within the last two years
- 6. Have not already attended a DRS appointment with this CHC

### Participant type(s)

Patient, Service user

### Age group

Mixed

### Lower age limit

18 Years

### Upper age limit

110 Years

### Sex

Both

### Target number of participants

330

### Key exclusion criteria

- 1. Are not registered to the Community Diabetes Education Program of Ottawa at the community health centre
- 2. Do not have T1DM or T2DM
- 3. Have not consented to virtual communications from CHC
- 4. Are not 18 years of age or older
- 5. Do not have an active chart (i.e., chart has been updated within the last two years
- 6. Have already attended a DRS appointment at this CHC

### Date of first enrolment

01/07/2025

### Date of final enrolment

01/11/2025

# Locations

### Countries of recruitment

Canada

# Study participating centre Centretown Community Health Centre

420 Cooper Street Ottawa Canada K1R 6H5

# Sponsor information

### Organisation

University Health Network

### Sponsor details

Manager Research Grants Research Solutions & Services University Health Network 700 University Avenue, 4th Floor - South Toronto Canada M5G 1X6

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evpresearch@uhn.ca

### Sponsor type

Hospital/treatment centre

### Website

https://www.uhn.ca

### **ROR**

https://ror.org/042xt5161

# Funder(s)

### Funder type

Research organisation

### **Funder Name**

Diabetes Action Canada

### Alternative Name(s)

Action Diabète Canada, DAC

### **Funding Body Type**

Government organisation

### **Funding Body Subtype**

Research institutes and centers

### Location

Canada

# **Results and Publications**

# Publication and dissemination plan

Planned publication in a peer-reviewed journal, planning to share results with knowledge users (e.g., community health professionals) via brief report or presentation.

# Intention to publish date

01/08/2026

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be stored in a publicly available repository (excluding forward sortation area, which will instead be reported as approximate distance to community health centre location). Data will be available for 10 years post publication.

# IPD sharing plan summary

Stored in publicly available repository