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A behaviour change technique reminder intervention for diabetic retinopathy screening

Submission date
18/06/2025

Recruitment status
No longer recruiting

Registration date
07/07/2025

Overall study status
Ongoing

Last Edited
16/12/2025

Condition category
Oral Health

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] 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?
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Contact information

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
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

Study type(s)
Efficacy, Screening

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(s)
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.

Key secondary outcome(s))
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

Completion date
30/04/2026

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

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
110 years

Sex
All

Total final enrolment
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

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

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file		04/06/2025	18/11/2025	No	No
Protocol file	version 2	10/12/2025	16/12/2025	No	No